

Keabsahan dan keberkesanan vaksin dalam menangani wabak COVID-19

IIUM COVID-19 Community Outreach Initiative



LEADING THE WAY

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Elakkan pandemik dalam panc



ANGKA kes harian baharu Covid-19 kira-kira 40,000 di Britain pada meningkat akibat tentangan sebahagian besar rakyatnya terhadap

Oleh Dzulkifli Abdul Razak 26 Ogos 2021, 9:00 am

Elakkan pandemik dalam pandemik

UJAM
BERHUIJAH
Oleh
Dzulkifli Abdul Razak

PANDEMIK Covid-19 terus menganas kebelakangan ini apabila angka harian mangsa yang dijangkiti melebihi 20,000 kes untuk beberapa hari berturut-turut. Begitu juga jumlah yang meninggal dunia turut meningkat, melebihi 14,000 orang bagi rakyat kita, nombor terbanyak selepas Indonesia.

Angka-angka ini dijangka terus meningkat di seluruh dunia terutama di negara-negara maju seperti Amerika Syarikat (AS), Britain, Jerman dan Portugal.

VARIAN DELTA

Ramai yang berasa aneh memandangkan negara-negara tersebut adalah antara yang teramai menerima suntikan vaksin Covid-19 secara besar-besaran berbanding negara membangun lain. Umumnya tidak sampai 10 peratus pun penduduk mereka menerima vaksin, sedangkan negara maju mencecah hampir 80 peratus. Namun, punca masalahnya agak berbeza, yakni berkaitan keberadaan satu lagi jenis virus Covid-19 dikenali sebagai varian Delta (DV).

Varian ini tercipta apabila virus Covid-19 asal dikatakan berusaha untuk mengelakkan daripada kesan suntikan yang dikenakan. Dalam hal ini, DV dijangka bersifat lebih dengan suntikan sedia ada. Maksudnya, DV tidak banyak terpengaruh oleh suntikan yang diberi dan sekali gus terus merebak dengan lebih cepat berbanding Covid-19 asal.

Dengan itu, lebih ramai pula yang akan terkesan dan kali ini tidak terhad kepada dewasa sahaja. Laporan kanak-kanak umur belasan juga terjejak dengan lebih mudah sedangkan bagi Covid-19 asal sebaliknya.

Kedudukan ini lebih mengusutkan kerana hampir kanak-kanak tidak mengalami suntikan anti-Covid-19 kerana

ANGKA kes harian baharu Covid-19 kira-kira 40,000 di Britain pada Julai lalu dijangka terus meningkat akibat tentangan sebahagian besar rakyatnya terhadap vaksin. - AFP

dikatakan kurang sesuai pada jangka usia agak muda. Oleh itu, mereka cukup terdedah kepada DV malah kini mula meningkat sedangkan bagi Covid-19 asal tidak begitu, yakni tiada peningkatan ketara.

Jelas, risiko kanak-kanak adalah tinggi bagi DV, bahkan dewasa yang belum disuntik lagi. Angka di Britain, anggaran 40,000 kes pada Julai lalu, diikuti AS (2,579 kes) antara Julai hingga Ogos berlaku peningkatan. Kemungkinan besar angka ini akan terus meningkat akibat tentangan yang berlaku terhadap vaksin oleh sebahagian masyarakat mereka khususnya. Oleh itu, apa yang dikenali sebagai 'pandemik dalam pandemik' yakni perkembangan DV memadam antara Covid-19 yang masih belum reda-reda setakat ini.

Ekoran itu, sasaran untuk mencapai imuniti atau kelainan kelompok menjadi lebih hambar mengikut pasaran oleh kerana faktor gangguan-gugat DV. Lazimnya imuniti kelompok dalam

“Varian Delta (DV) dijangka bersifat lebih lasak lagi apabila bertembung dengan suntikan sedia ada.”

sebagai suatu penurunan jangkitan virus atau penyakit berkaitan apabila kelainan mencapai peratusan tinggi secara semula jadi atau sebaliknya. Seandainya ini tercapai bermakna ia berlaku juga untuk DV yakni kelainan bagi kedua-duanya. Maka wabak DV masih tidak terkawal sepenuhnya dan kelompok yang disasarkan terus terdedah kepada bahaya DV termasuk maut.

DOS TAMBAHAN

Oleh demikian, pihak pembuat vaksin bergegas untuk mencipta suntikan baharu khusus untuk DV sahaja atau menawarkan dos tambahan kepada suntikan

sedia ada. Malah cubaan ini sudah pun terbuka dan ada pihak tertentu - negara atau persatuan menguar-uarkannya secara rasmi. Pun begitu, jika ada suntikan khususnya DV sekali pun, hakikat yang masih ramai warganegara membangun masih belum mendapat suntikan Covid-19 asal tidak memberi apa-apa jaminan akan tercapainya apa-apa kelainan kelompok. Setakat ini, walaupun belum ada keputusan muktamad dalam hal tersebut, besar kemungkinan pandemik DV dalam pandemik Covid-19 terus membingkaskan semua pihak terutama golongan kanak-kanak.

Kesimpulan daripada kesemua ini adalah pandemik yang ada tidak akan reda dalam masa terdekat. Sebaliknya, mungkin ada satu lagi pandemik berlaku jika kawalan bagi kedua-duanya agak longgar dan tidak dipenuhi seketat mungkin. Begitu juga dengan program suntikan vaksin kepada warga masing-masing walaupun ada bantuan kepada negara yang amat memerlukan. Ini adalah kerana gelagat sebahagian masyarakat yang enggan

patuh kepada peraturan dikenakan untuk melindungi semua.

Mereka mengusutkan lagi keadaan termasuklah kumpulan yang ingin mengharamkan penggunaan vaksin dan menyalahi status 'harus' yang telah rata-rata diterima semua pihak berwajib sebagai fatwa rasmi.

Golongan guru yang menolak vaksin seperti dilaporkan baru-baru ini di selatan Semenanjung mesti kerana mereka akan mengauli para pelajar lambat laun. Dan mungkin menjadi perebak dan mengancam jiwa anak-anak muda tidak berdos ini.

Apatah lagi dalam keadaan DV merebak dengan pesatnya tanpa sebarang hambatan untuk mengelakkan berlakunya tragedi pandemik dalam pandemik yang mengertikan. Dengan itu, amat wajar sekali setiap individu mengambil iktibar sewajarnya agar kita terus berwaspada jua dalam menunaikan fardu kifayah untuk rahmatan lil alamin.

PROFESOR Emeritus Tan Sri Dzulkifli Abdul Razak ialah Rektor Universiti Islam Antarabangsa Malaysia (UIAM).

1 Mengapa kita perlu pada vaksin



Asst Prof Dr Syed Abdul Khaliq

- MBBS (IIUM)
- M.Med Paediatrics (USM)
- Fellowship in Neonatology (RCPCH UK)
- Pakar Perubatan Pediatrik & Neonatologi, Kulliyyah Perubatan, International Islamic University Malaysia



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2 Pembuatan dan pembangunan vaksin



Prof. Dr. M. Taher Bin Bakhtiar

- Ph.D in Bioprocess - Doctor of Philosophy, Universiti Teknologi Malaysia (UTM)
- Master in Organic Chemistry - Masters Degree, Universiti Teknologi Malaysia (UTM)
- Bachelor in Pharmacist - Bachelor Degree, Universitas Andalas



2 Pembuatan dan pembangunan vaksin



Assoc. Prof. Dr. Mohamad Haniki Bin Nik Mohamed

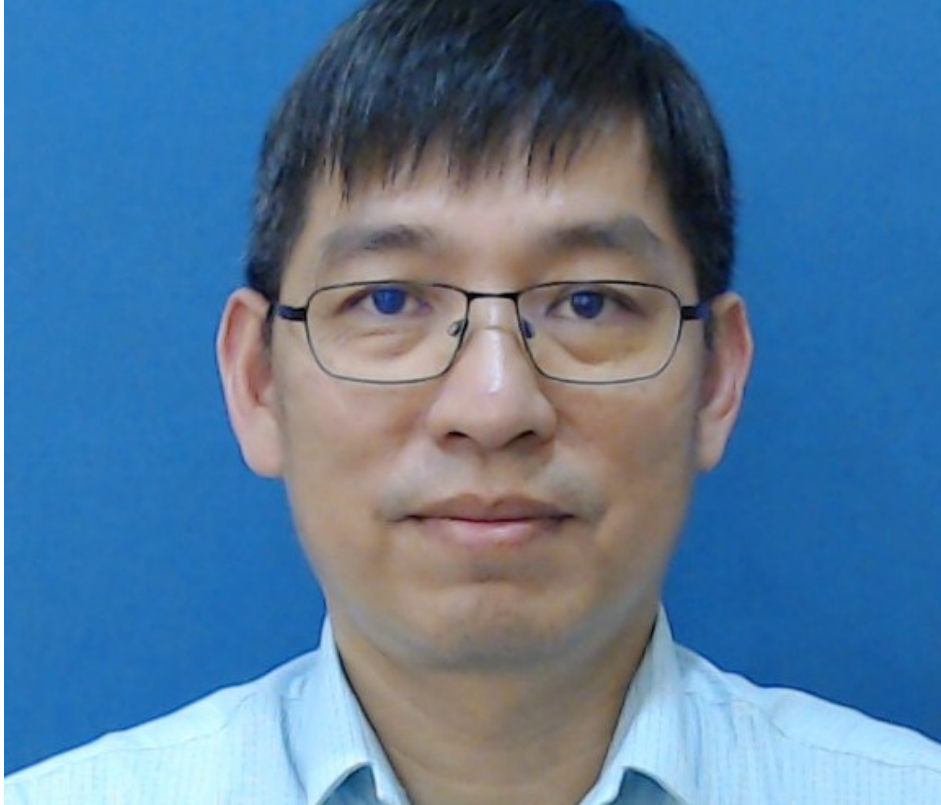
- Ph.D in Pharmacy - Doctor of Philosophy, University of Tennessee
- Bachelor in Pharmacy - Bachelor Degree, Universiti Sains Malaysia (USM)
- Certificate program in Global Tobacco Control - Certificate, Johns Hopkins Bloomberg School of Public Health



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3 Keberkesanan vaksin



Prof. Dr. How Soon Hin

- Master of Internal Medicine - Masters Degree (Clinical Specialist), Universiti Malaya (UM)
- Ijazah Sarjana Muda Perubatan dan Sarjana Muda Pembedahan (MBBS) - Masters Degree, Universiti Malaya (UM)
- Pakar Perunding Perubatan Respiratori



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3 Keberkesanan vaksin



Prof. Dr. Jamalludin Ab Rahman

- Master in Community Medicine (Epidemiology & Statistic) - Masters Degree (Clinical Specialist), Universiti Kebangsaan Malaysia (UKM)
- Degree of Medicine - Universiti Kebangsaan Malaysia (UKM)
- Medical Science - Universiti Kebangsaan Malaysia (UKM)
- Pakar Perubatan Kesihatan Awam (Epidemiologi dan Statistik Perubatan)
- Fellow Public Health Medicine Malaysia
- Exco Persatuan Pakar Perubatan Kesihatan Awam



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4 Keselamatan vaksin



Asst. Prof. Dr. Norhidayah Binti Kamarudin

- Master of Medicine (Microbiology) - Masters Degree (Clinical Specialist), UKM
- Bachelor of Medicine and Bachelor of Surgery - IIUM
- Pakar Patologi (Mikrobiologi Klinikal)



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4 Keselamatan vaksin



Assoc. Prof. Dato' Dr. Ahmad Fadzil Bin Abdullah

- Doctor - Masters Degree (Clinical Specialist), UKM
- Degrees of Bachelor of Medicine and Bachelor of Surgery - Bachelor Degree, UM
- Pakar Perunding Respiratori Perubatan Kanak-kanak



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(Company No. 101067-P)

الجامعة الإسلامية العالمية ماليزيا
INTERNATIONAL ISLAMIC UNIVERSITY MALAYSIA
يُونِيسَيْتِي اِسْلَامُ اِنْتَارَا اِنْجَسَا مِلْسِيَا

Garden of Knowledge and Virtue

KULLIYAH OF MEDICINE

Kenapa perlu pada vaksin?

Asst Prof Dr Syed Abdul Khaliq

MBBS (IIUM), M.Med Paediatrics (USM),
Fellowship in Neonatology (RCPCH UK)

Pakar Perubatan Pediatrik & Neonatologi
International Islamic University Malaysia

DEATH TOLL

200M
Black Death
(Bubonic Plague)
1347-1351

56M
Small Pox
1520

40-50M
Spanish Flu
1918-1919

30-50M
Plague of Justinian
541-542

25-35M
HIV/AIDS
1981-present

12M
The Third
Plague
1855

5M
Antonine Plague
165-180

3M
17th Century
Great Plagues
1665

1.1M
Asian Flu
1665

1M
Russian Flu
1889-1890

1M
Hong Kong Flu
1968-1970

1M
Cholera 6
outbreak
1817-1923

1M
Japanese
Smallpox
Epidemic
735-737

600k
18th Century
Great Plagues
1817-1923

200k
Swine Flu
2009-2010

100-150k
Yellow Fever
Late 1800s

11.3k
Ebola
2014-2016

~8.3k
Coronavirus
(COVID-19)
2019-present

850
MERS
2019-present

770
SARS
2002-2003

Rekod kematian disebabkan
oleh pandemik

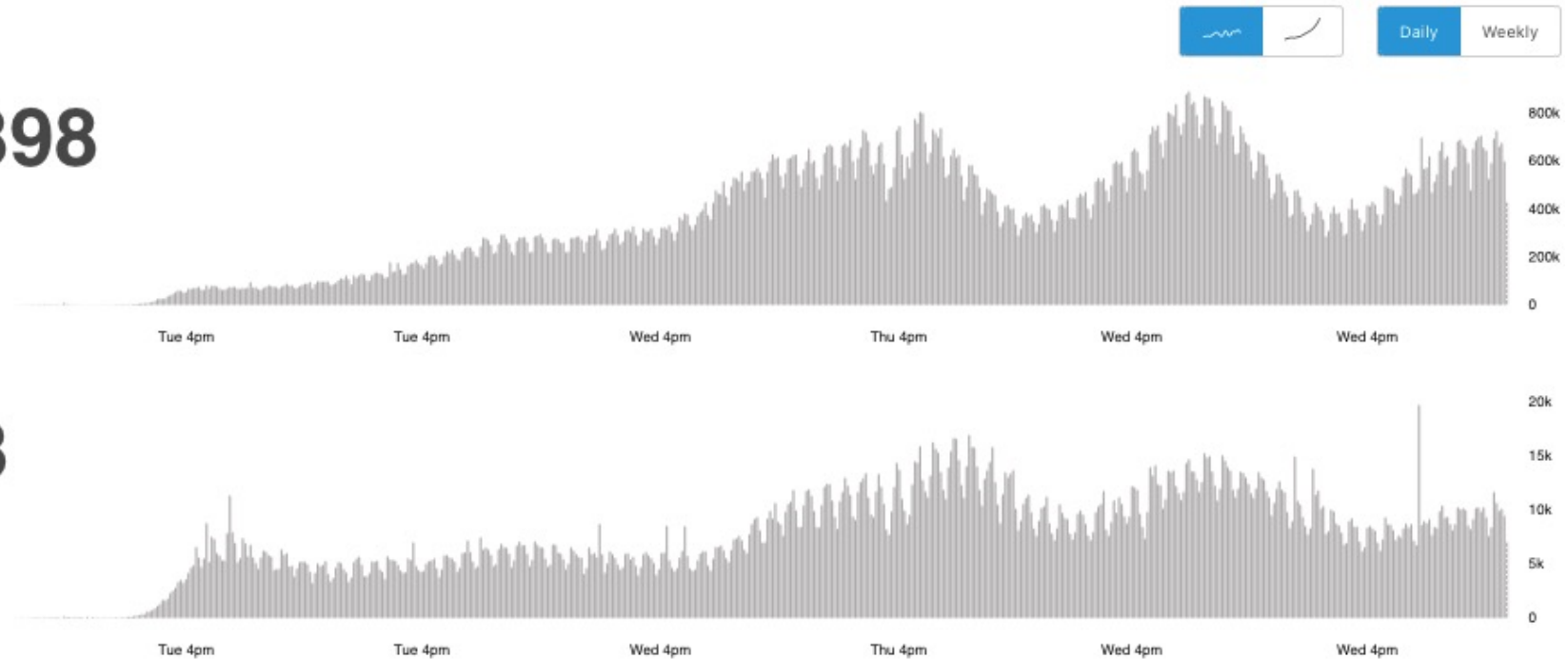
Beban Covid-19 pada Dunia (24 Ogos 2021)

Global Situation

212,357,898
confirmed cases

4,439,843
deaths

Source: World Health Organization
Data may be incomplete for the current day or week.



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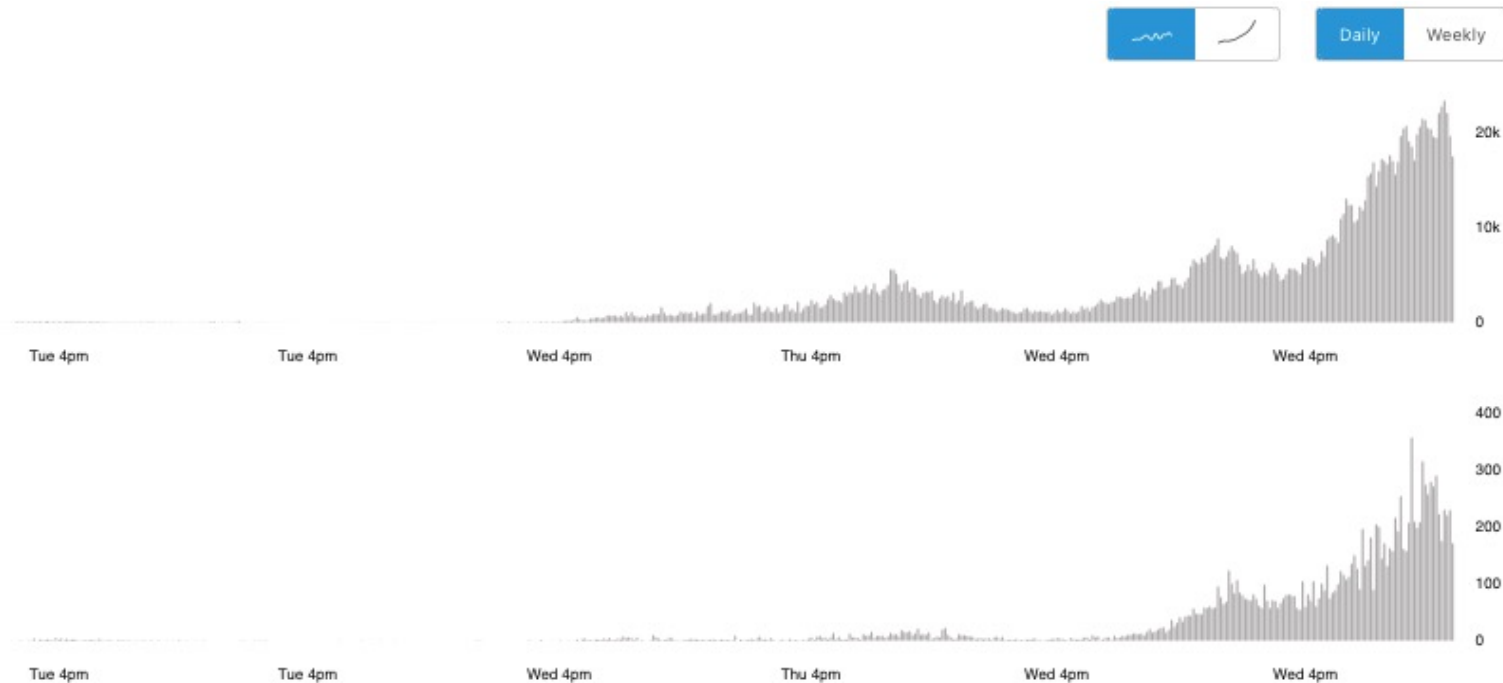
Beban Covid-19 pada Malaysia (24 Ogos 2021)

Malaysia Situation

1,572,765
confirmed cases

14,342
deaths

Source: World Health Organization



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Beban Covid-19 pada Malaysia



Apa maknanya?

Jumlah kesemua rakyat Malaysia 2021 : 32.75 Juta

Setiap 100 rakyat Malaysia, 5 orang pernah dijangkiti covid

Setiap 1000 rakyat Malaysia, 8 orang masih aktif covid

Setiap 1000 kes aktif, 4 orang di ICU

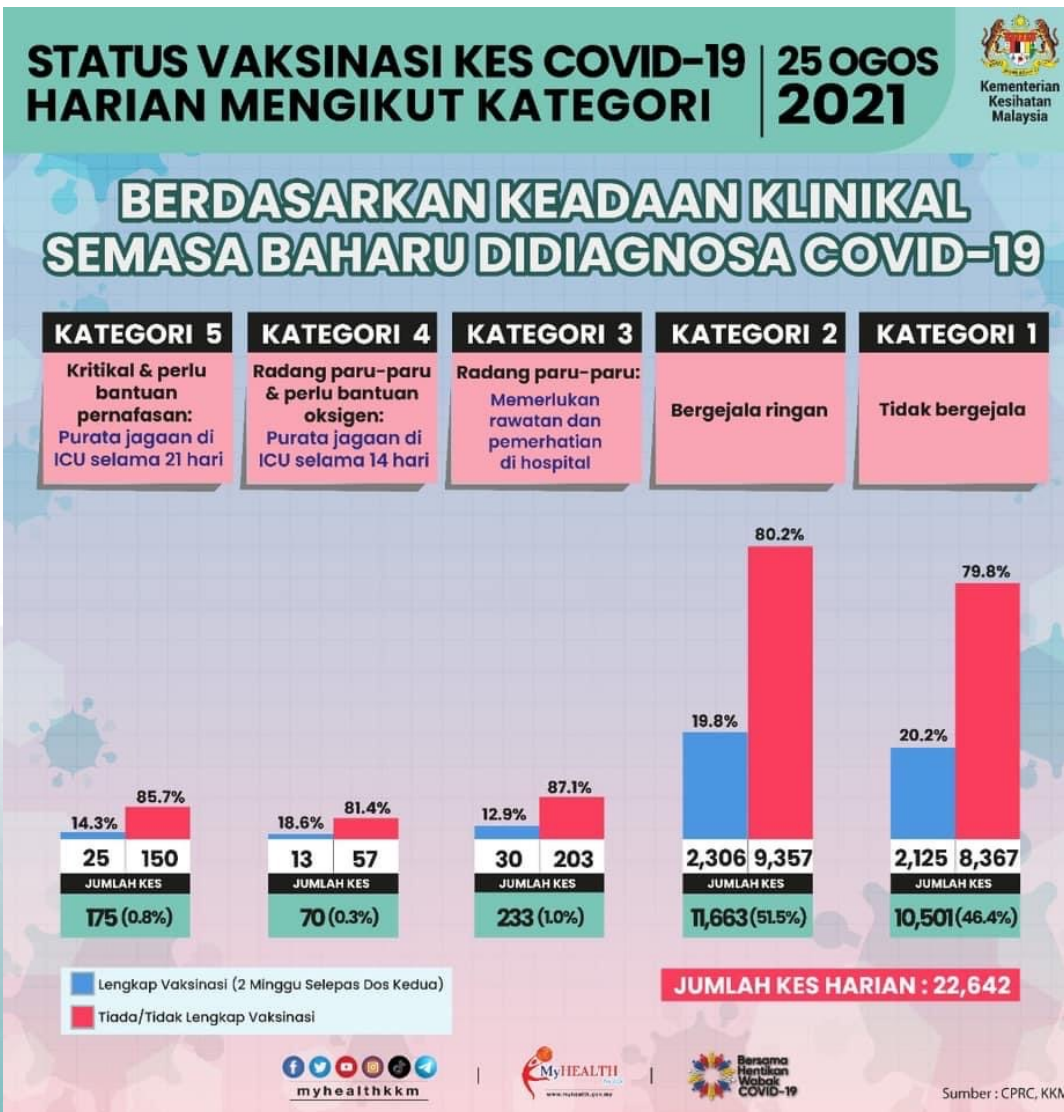
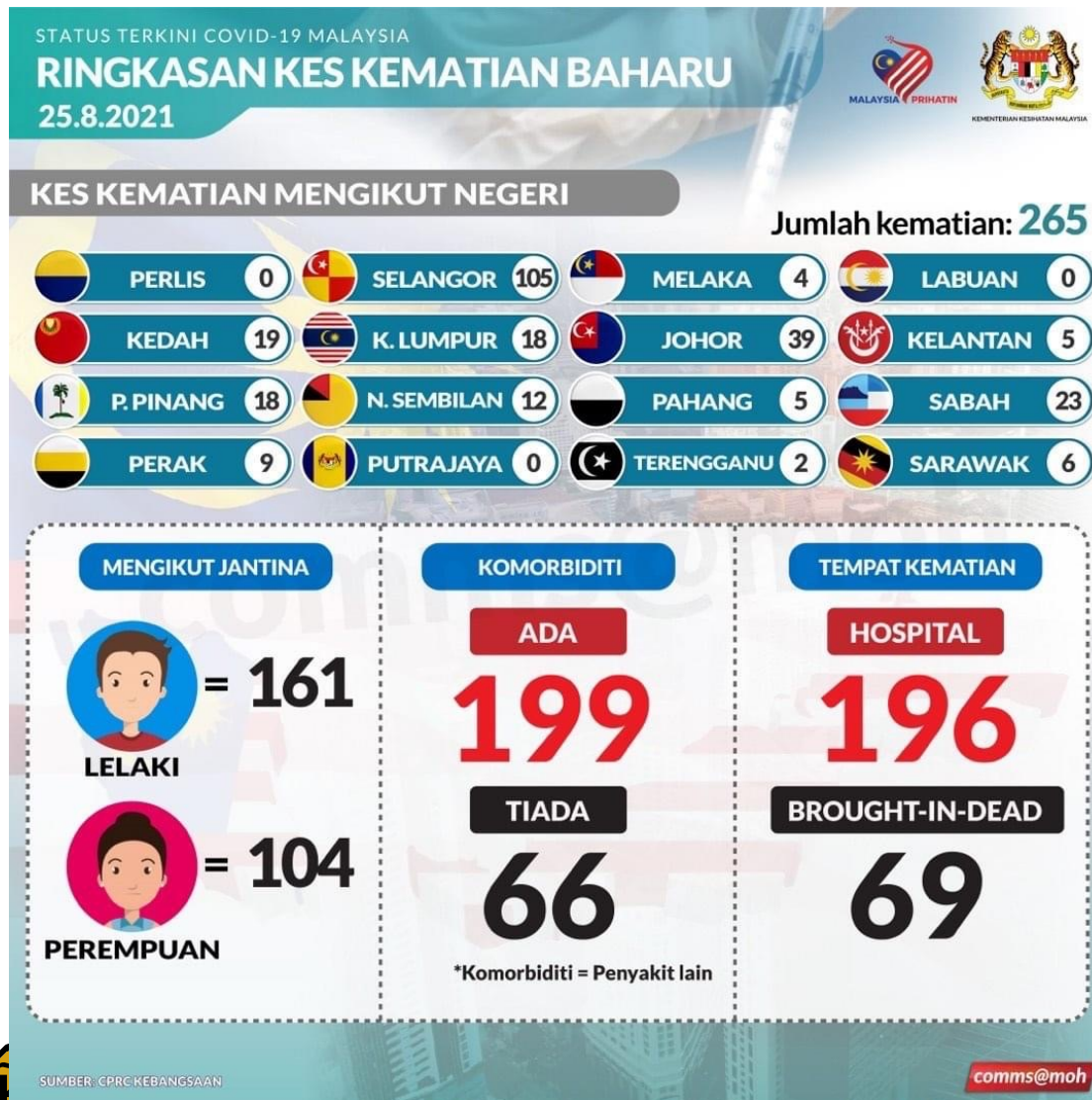
49% yang berada di ICU memerlukan bantuan alat pernafasan

Setiap 1000 kes covid di Malaysia, 9 orang mati

Setiap 10,000 rakyat Malaysia, 5 orang mati sebab covid



Beban Covid-19 pada Malaysia



Kehilangan Tokoh

- IIUM
 - Dr Mohamad Idries Ahmed (KLM)
 - Prof Dr Aahad Osman Gani
 - Dr Roziana
 - Mdm Zuriana Ab Rani (RSD)
 - Br Zahirul Islam (3rd yr KICT)
- Tokoh Malaysia
 - Tan Sri Harussani
 - A. Abdul Hakim Mazhar





إِنَّا لِلّٰهِ وَإِنَّا إِلَيْهِ رَاجِعُونَ

Prof. Dr. AAhad Osman-Gani

**Former Dean and Managing Director,
IIUM Academy of Graduate and Professional Studies**



إنا لله وإنا إليه راجعون

Br. Khairil Azhar Md Yassin

Former Academic Member, Department of Sociology and Anthropology, KIRKHS, IIUM

اللَّهُمَّ اغْفِرْ لَهُ، وَارْحَمْهُ وَعَافِهِ، وَاعْفُ عَنَّهُ، وَأَكْرِمْ نُزُلَهُ، وَوَسِّعْ مَدْخَلَهُ، وَاعْسِلْهُ بِالْمَاءِ وَالتَّلْجِ وَالْبَرَدِ، وَنَقِّهِ مِنَ الْخَطَايَا كَمَا نَقَّيْتَ 1 الثَّوْبَ الْأَبْيَضَ مِنَ الدَّنَسِ، وَأَبْدِلْهُ دَارًا خَيْرًا مِنْ دَارِهِ، وَأَهْلًا خَيْرًا مِنْ أَهْلِهِ، وَأَدْخِلْهُ الْجَنَّةَ، وَفِيهِ فِئْتَةُ الْقَبْرِ وَعَذَابُ النَّارِ

O Allah! Forgive him and have mercy on him. Grant him ease and respite. Make his resting place a noble one, and facilitate his entry. Wash him with the most pure and clean water, snow and hail. Purify him from sins as a white garment is cleansed of dirt. Give him in exchange a home better than his home (on earth) and a family better than his family. Grant him entrance to Paradise and protect him from the trials of the grave and the torture of Hell Fire.



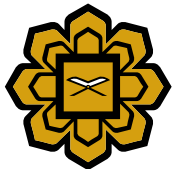
إنا لله وإنا إليه راجعون

Dr. Mohamed Idries Ahmed

Lecturer, Department of Arabic, Kulliyah of Languages & Management, IIUM

اللَّهُمَّ اغْفِرْ لَهُ، وَارْحَمْهُ وَعَافِهِ، وَاعْفُ عَنَّهُ، وَأَكْرِمْ نُزُلَهُ، وَوَسِّعْ مَدْخَلَهُ، وَاعْسِلْهُ بِالْمَاءِ وَالتَّلْجِ وَالْبَرَدِ، وَنَقِّهِ مِنَ الْخَطَايَا كَمَا نَقَّيْتَ 1 الثَّوْبَ الْأَبْيَضَ مِنَ الدَّنَسِ، وَأَبْدِلْهُ دَارًا خَيْرًا مِنْ دَارِهِ، وَأَهْلًا خَيْرًا مِنْ أَهْلِهِ، وَأَدْخِلْهُ الْجَنَّةَ، وَفِيهِ فِئْتَةُ الْقَبْرِ وَعَذَابُ النَّارِ

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NASIONAL

'Kematian ulama berturut-turut satu musibah'

Samadi Ahmad

bhnews@bh.com.my

May 30, 2021 @ 8:20pm



Menteri di Jabatan Perdana Menteri (Hal Ehwal Agama),
Datuk Dr Zulkifli Mohamad Al-Bakri

Long Covid

- Fatigue (mudah penat)
- Sesak nafas
- Sakit dada
- Masalah memori, masalah konsentrasi
- Insomnia
- Pening/sakit kepala
- Tinnitus
- Sakit sendi
- Masalah saraf



Kesan Ekonomi

- Kejatuhan ekonomi paling teruk sejak Perang Dunia ke2
- Ekonomi global mengecut 3.5%
- Keperluan sokongan fiskal; hamper 16 Trillion USD
- Kehilangan pekerjaan dan mata pencarian – lebih teruk pada pekerjaan kemahiran rendah, dan negara pertengahan

Social and Economic impact of covid-19. Brookings Global Working Paper 158. June 2021.



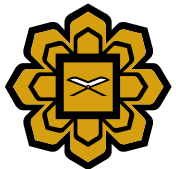
Kesan Sosial

- Malaysia 7 July 2021 – 468 kes bunuh diri dalam 5 bulan 2021, berbanding dengan 631 (2020), 609 (2019)
- Yatim piatu sebab covid:
 - Malaysia : 33 Kanak-kanak jadi Yatim piatu (KPWKM)
 - Global (dari 1/3/2020 – 30/4/2021)
 - 1,134,000 kanak-kanak kehilangan penjaga utama
 - 1,562,000 kehilangan penjaga utama atau sekunder

Global minimum estimates of children affected by COVID-19-associated orphanhood and deaths of caregivers: a modelling study, Hillis, Susan D et al., The Lancet, Volume 398, Issue 10298, 391 - 402



Kenaikan kes bunuh diri



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THE STRAITS TIMES
Malaysia sees rise in
suicides and calls to
helplines amid Covid-19
pandemic



Police recorded 468 suicides in the first five months of 2021, compared to 631 in 2020 and 609 in 2019. PHOTO: EPA-EFE



Hazlin Hassan
Malaysia Correspondent

UPDATED JUL 12, 2021, 4:09 PM

KUALA LUMPUR - Having been diagnosed with depression since she was a teenager, online retailer Nina Razif, 35, had learnt to

**Suicide rising in
Malaysia due to
hardships amid
coronavirus pandemic**

Police records 468 suicides from January to May

Pizaro Gozali Idrus | 03.07.2021



Selangor, Malaysia (Syaiful Redzuan - Anadolu Agency)

JAKARTA, Indonesia

Malaysian Muslim youth group voiced concern on
lay about rising suicides in the country amid the
navirus pandemic.

COVID-19: Lima beradik kini yatim piatu

June 8, 2021 @ 9:23am

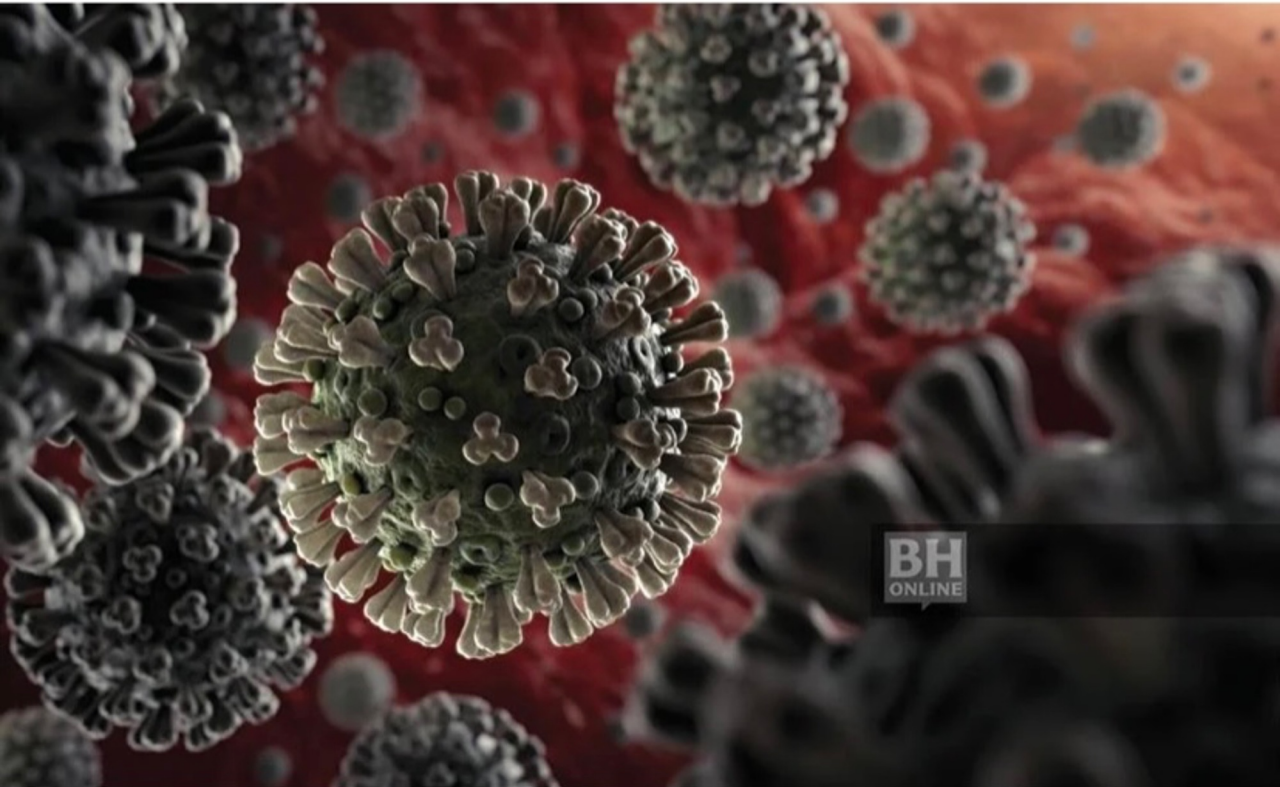


Foto hiasan

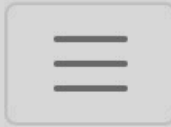
EDISI

10 beradik yatim piatu angkara Covid-19

13 Aug 2021



Ketua Operasi Daerah Petaling, Muhammad Sharil Ritin (kiri) menyerahkan sumbangan makanan kepada keluarga berkenaan.



AM

33 kanak-kanak yatim piatu akibat COVID-19



Menteri Pembangunan Wanita, Keluarga dan Masyarakat Datuk Seri Rina Harun (kiri) beramah mesra bersama dua orang kanak-kanak Rumah Kanak-Kanak Pokok Sena ketika mengadakan tinjauan dan pemantauan di sini, hari ini.

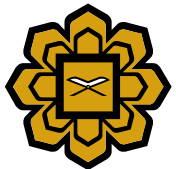


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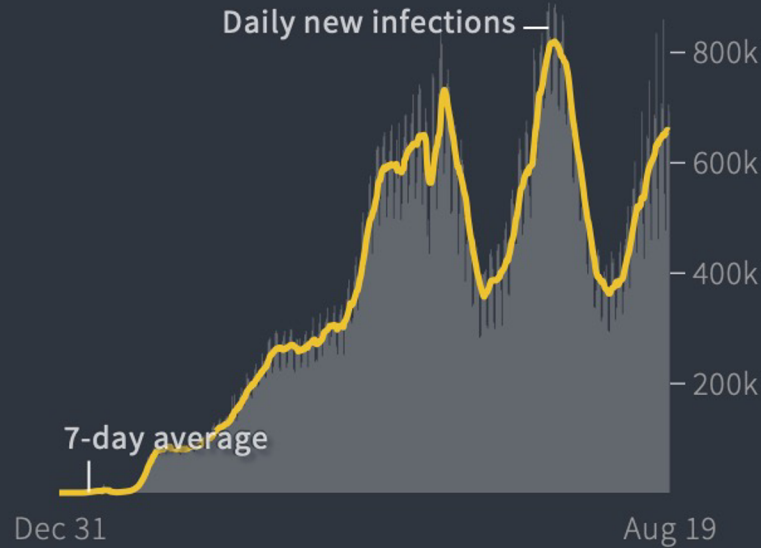
COVID tidak akan berakhir dalam masa terdekat

- ❓ Mutasi sentiasa berlaku selagi ada jangkitan baru
- ❓ Varian baru berpotensi untuk lebih infektif dan bahaya



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New reported infections



Countries reporting the most new infections each day *

▲ **UNITED STATES** 145,625



▲ **IRAN** 35,944



▼ **INDIA** 33,828



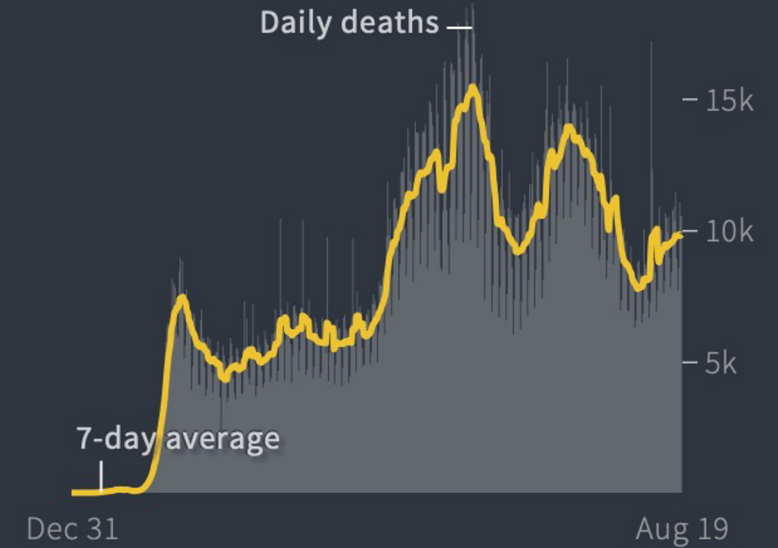
▲ **UNITED KINGDOM** 31,040



▼ **BRAZIL** 29,871



Reported deaths



Countries reporting the most deaths each day *

▼ **INDONESIA** 1,269



▲ **UNITED STATES** 985



▼ **BRAZIL** 807



▲ **RUSSIA** 800

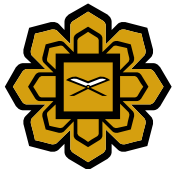


▲ **MEXICO** 667



COVID tidak akan berakhir dalam masa terdekat

Varian Delta telah menyebabkan penambahan 60% kes di seluruh dunia



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The Delta variant may be taking hold in parts of Europe and North America

Modelled estimates of the Delta variant's share of all sequenced cases (%)



*More than 90% of Russia's sequenced cases of Delta are from Saint Petersburg

Source: FT prevalence estimates based on data from GISAID, Sciensano, Belgian National Reference Laboratory

Method from Tom Wenseleers / @TWenseleers

© FT

“

Perlunya satu penyelesaian
tuntas, supaya kita dapat hidup
dengan covid-19

”



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(Company No. 101067-P)

الجامعة الإسلامية العالمية ماليزيا
INTERNATIONAL ISLAMIC UNIVERSITY MALAYSIA
يُونِيسَيْتِي إِسْلَامُ إِنْتَارَايْجُسِيَا مِلْسِيَا

Garden of Knowledge and Virtue

KULLIYAH OF MEDICINE

Pembuatan dan pembangunan vaksin

5 fakta tentang vaksin

1. Vaksin selamat dan berkesan
2. Vaksin mencegah penyakit yang mengancam nyawa
3. Vaksin memberi kekebalan yang lebih baik daripada jangkitan semula jadi
4. Vaksin gabungan ialah selamat dan bermanfaat
5. Sekiranya program vaksinasi/imunisasi dihentikan penyakit tertentu akan kembali



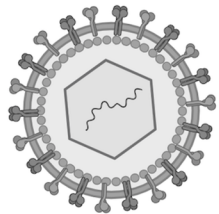
Bahagian virus/mikroorganisma yang boleh dijadikan sebagai material vaksin

Approaches to Viral Vaccine Development

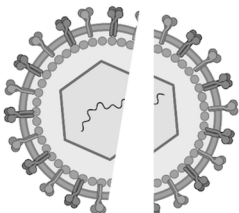
a. Live attenuated



b. Whole inactivated



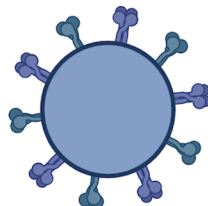
c. Split inactivated



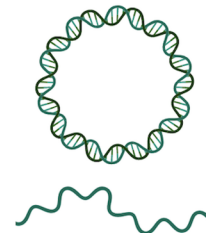
d. Synthetic peptides



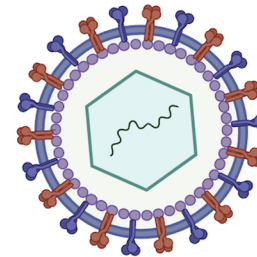
e. Virus-like particles



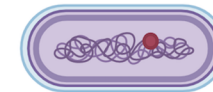
f. DNA or RNA



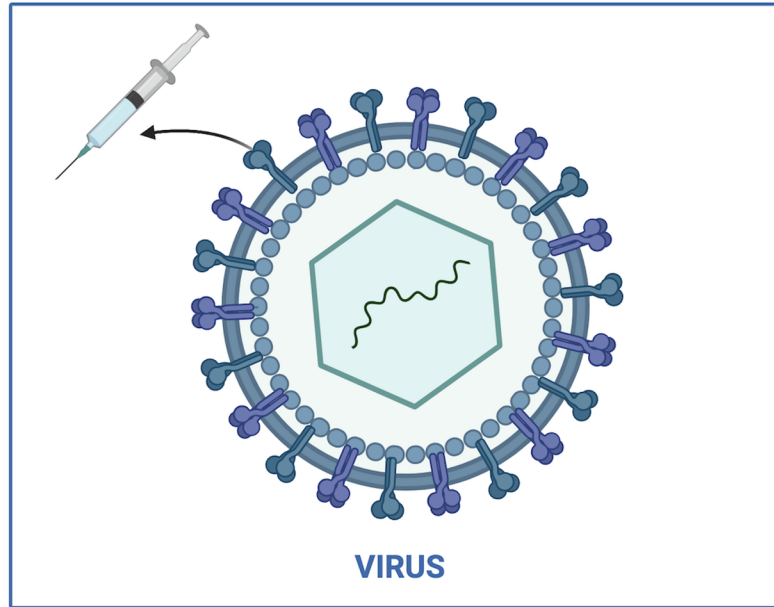
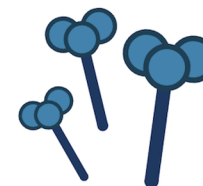
i. Recombinant viral vectors



h. Recombinant bacterial vectors
























g. Recombinant subunits



Perbandingan vaksin

How some of the Covid-19 vaccines compare

Company	Type	Doses	Storage
 Oxford Uni-AstraZeneca	Viral vector (genetically modified virus)	x2 	 2 to 8°C (6 months)
 Moderna	RNA (part of virus genetic code)	x2 	 -25 to -15°C (7 months)
 Pfizer-BioNTech	RNA	x2 	 -80 to -60°C (6 months)
 Gamaleya (Sputnik V)	Viral vector	x2 	 -18.5°C (liquid form) 2 to 8°C (dry form)
 Sinovac (CoronaVac)	Inactivated virus	x2 	 2 to 8°C
 Novavax	Protein-based	x2 	 2 to 8°C
 Janssen Johnson & Johnson	Viral vector	x1 	 2 to 8°C (3 months)

Source: UK government, Reuters

BBC



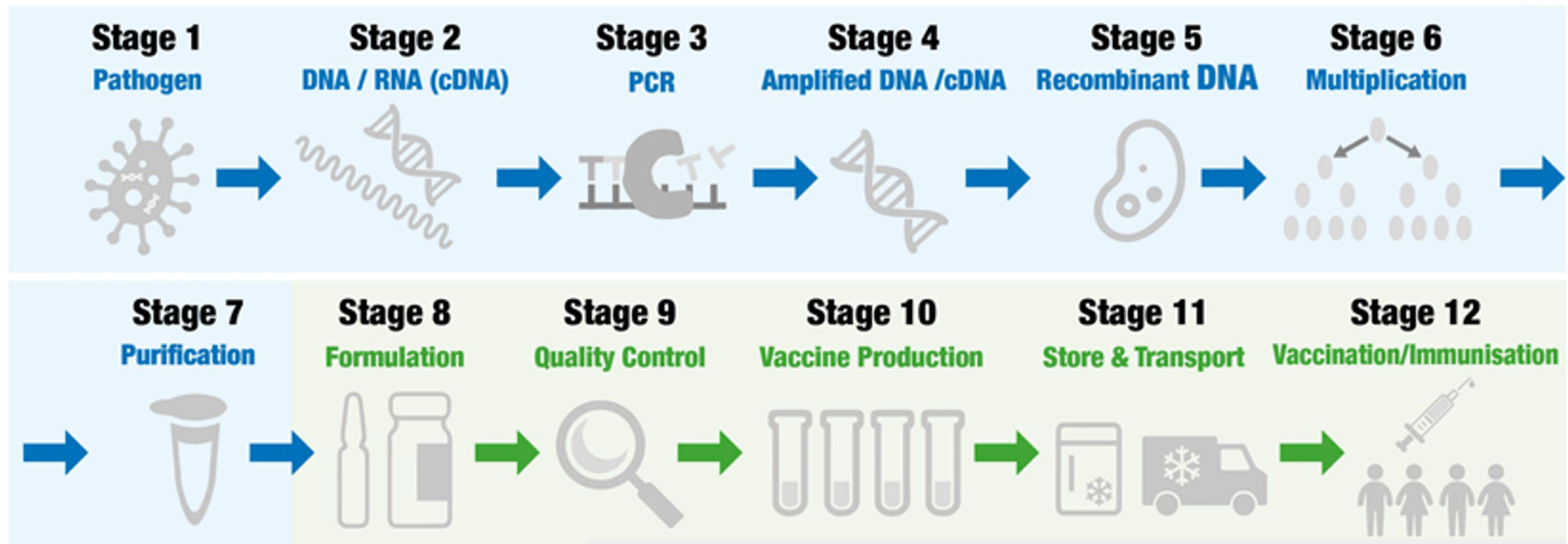
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<https://www.bbc.com/news/world-europe-56275342>

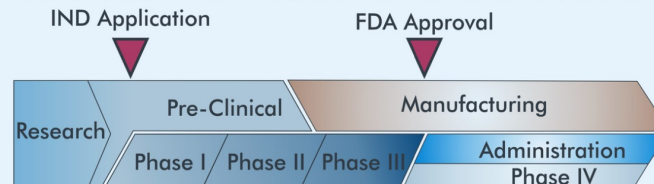
Pembuatan Vaksin Secara Am

VACCINE RESEARCH & DEVELOPMENT - FROM START TO FINISH



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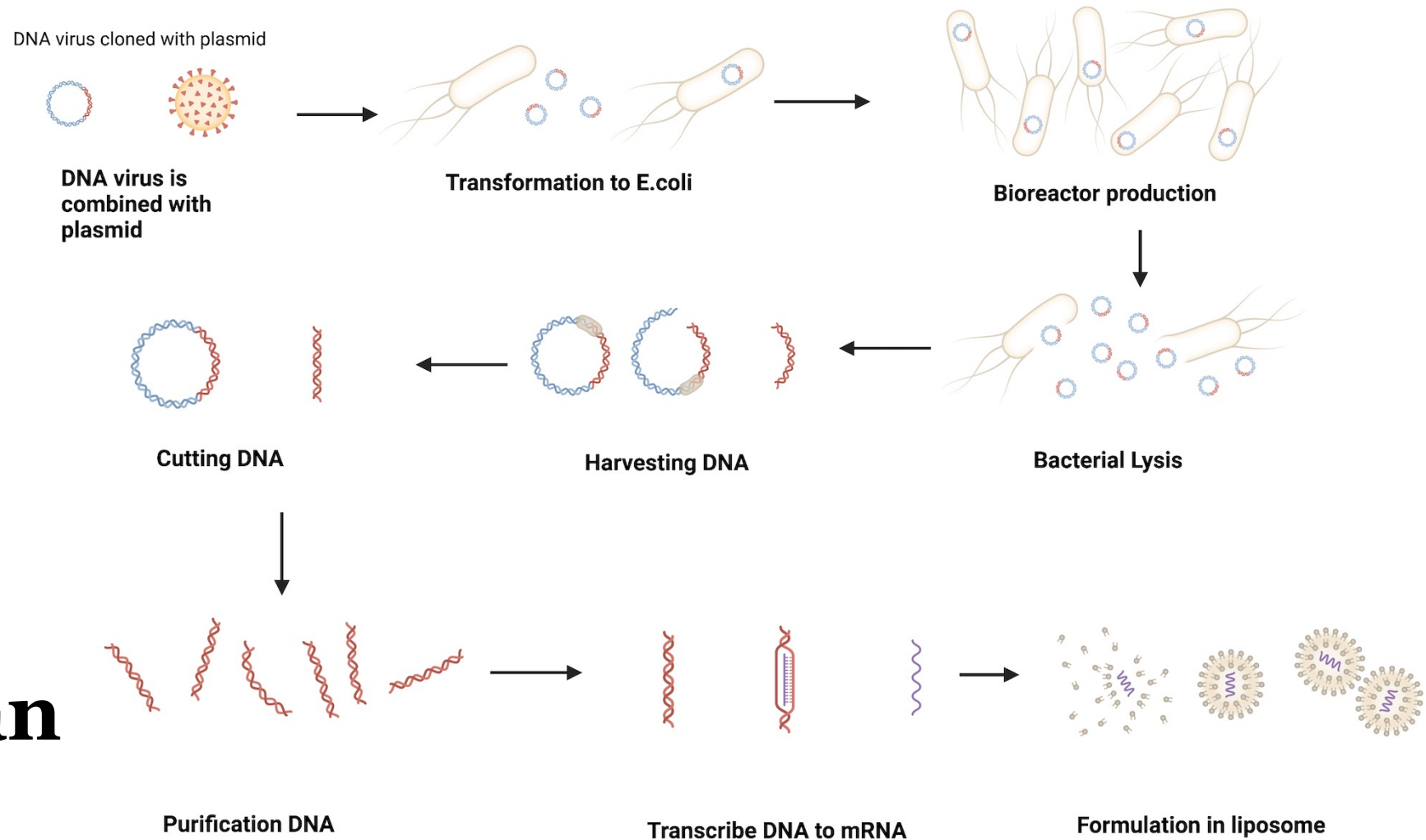
Pandemic Accelerated Model



€93 Billion Spent By Public Sector On COVID Vaccines and Therapeutics in 11 Months, Research Finds

Health Systems 12/01/2021 • Madeleine Hoecklin

Kaedah penghasilan mRNA

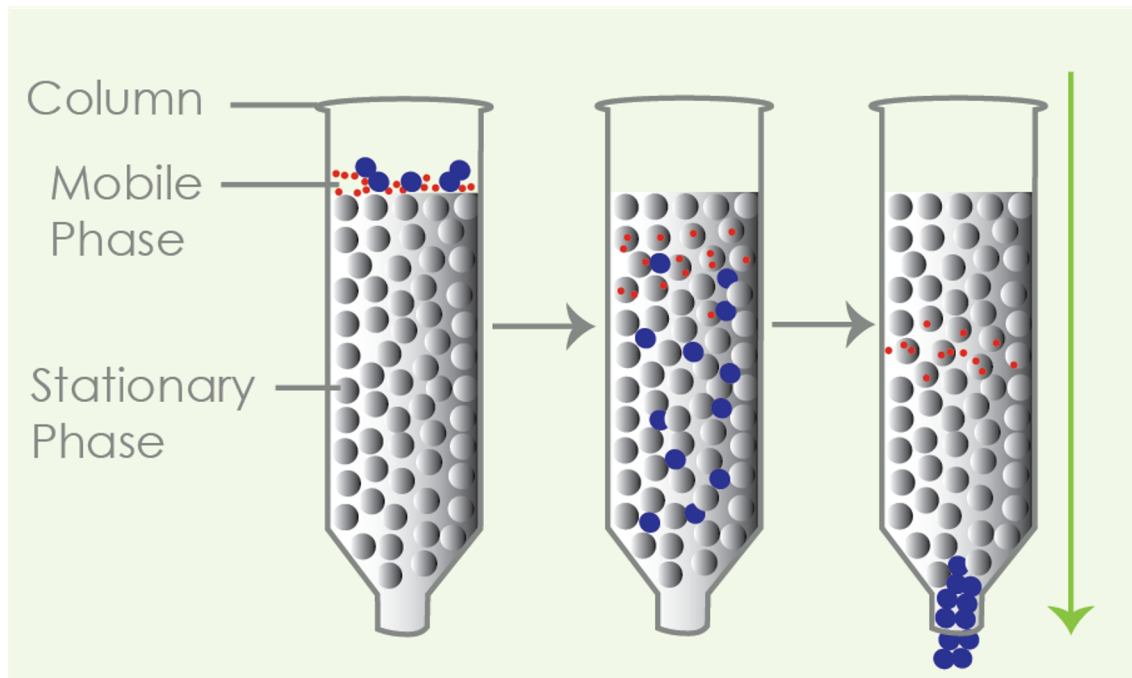


Penulenan vaksin

- Fasa diam berupa penyerap, penyah cas, hydrophobic interaction, mixed mode, size exclusion, atau berasaskan affinity.
- Fasa bergerak (pelarut air/buffer)
- Semua bahan akan yang tidak diperlukan akan diasingkan dan hanya vaksin tulen sahaja yang akan di gunakan

Column Chromatography

GOLDBIO



Vaksin tulen



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Komponen vaksin dalam formulasi

- Virus/bahagian dari virus/produk virus
- Adjuvant
 - ✦ Bahan kimia untuk meningkatkan keberkesanan vaksin, contoh: aluminium salts (hydroxide, phosphate)
- Penghantaran (delivery)
 - ✦ Emulsi, liposome (kolesterol dan fosfolipid) atau
 - ✦ Adenovirus carrier
- Air injeksi



Pfizer Biontech vaccine-mRNA vaccine

- **DNA dihasilkan dengan bakteri Escherichia coli**
- **Bahan aktif:**
 - mRNA (messenger ribonucleic acid)
- **Pembawa vaksin**
 - ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)
 - 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)
 - Distearoylphosphatidylcholine (DSPC)
 - Cholesterol
- **Bahan penyokong**
 - potassium chloride
 - monobasic potassium phosphate
 - sodium chloride
 - dibasic sodium phosphate dihydrate
 - sucrose
 - sterile water for injection



Pembawa vaksin



AstraZeneca-Recombinant vaccine

- Virus dibiakan dengan HEK-293 cells (human cells)
- **Bahan aktif:**
 - 🚢 recombinant glycoprotein
- **Bahan penyokong:**
 - 🚢 L-histidine (penstabil)
 - 🚢 L-histidine hydrochloride monohydrate
 - 🚢 Magnesium chloride hexahydrate
 - 🚢 Polysorbate 80 (E 433) (surfaktan)
 - 🚢 Ethanol
 - 🚢 Sucrose
 - 🚢 Sodium chloride
 - 🚢 Disodium edetate dihydrate
 - 🚢 Water for injections



Sinovac- inactivated virus

- Virus dibiakkan dengan Vero cells
- **Bahan aktif:**
Inactivated SARS-CoV-2 antigen
- **Adjuvant:**
Aluminum hydroxide
- **Bahan-bahan penyokong:**
Disodium hydrogen phosphate
Sodium dihydrogen phosphate
Sodium chloride



Isu Halal

- Halal isu dalam pengasilan vaksin ialah dalam penggunaan **enzim** dalam pengkulturan sel, akan tetapi ada juga enzim yang bukan berunsur porcine tetapi dari bakteria.
- Jika ada unsur enzim dalam penghasilan vaksin, telahpun dinyahkan dalam proses **penulinan** menggunakan kaedah “kromatografi” yang bersifat menyerap bahan bahan tersebut.
- Sedangkan untuk stabilizer, buffer dan adjuvants tiada isu kehalalan yang perlu di ragukan.



Keberkesanan Vaksin

Prof Dr How Soon Hin
Pakar Perubatan Respiratori
Kulliyyah Perubatan, IIUM

Prof Dr Jamalludin Ab Rahman
Pakar Epidemiologi & Biostatistik
Kulliyyah Perubatan, IIUM

- Ujian klinikal fasa 3 - vaksin sangat berkesan untuk mengelak kematian dan penyakit teruk dengan keberkesaan hampir 100%
- Negara-negara maju bermula program vaksinasi sejak hujung tahun 2020

COVID19 Vaccine Update- June 4, 2021
By: Your Local Epidemiologist

	Authorized for Emergency Use in the U.S.						Natural Infection
	Pfizer	Moderna	J&J One-Dose	AstraZeneca	Novavax	J&J Two-Dose	
Biotechnology	mRNA	mRNA	Adenovirus	Adenovirus	Recombinant protein	Adenovirus	Virus
Months of available data	6 months	6 months	3 months				8 months
Symptomatic COVID19	Overall efficacy (old variants)	Adults 95% (clinical trial) 90-91%; 80-85% after dose 1 (real world) Adolescents 100% (clinical trial)	94.1% (clinical trial) 90%; 80% after dose 1 (real world) Adolescents 96% (clinical trial)	66.1% (global clinical trial) 72.0% (U.S. clinical trial) 76.7% (real world)	U.S.: 76% (clinical trial) Global: 62% (clinical trials) 67% (real world) 82% when doses were ≥12 weeks apart and 55% when doses were <6 weeks apart	96.4%	80-90% protected from reinfection. Waning antibody levels can occur within several months
	Efficacy (old variants) among 65+ Alpha (UK) variant	92.9% (65-75 years) 100% (75+ years) 87-95% efficacy	100% No impact on efficacy	68.6% (global) 74% efficacy (clinical trials) 66% efficacy (UK)	85% 86.3% efficacy		50% protected from reinfection Natural infection works (2.4-fold decrease in NA; T-cells work)
	Beta (S. Africa) variant	72-75% efficacy	Vaccine works (6-fold decrease in NA; T-cells working)	52-57% efficacy	~10-22% efficacy (9.5-fold decrease in NA)	55.4% efficacy among HIV- participants; 48.6% overall	<i>Non-hospitalized from original infection:</i> reduced-to-no antibody protection <i>Hospitalized from original infection:</i> protection similar to vaccine; T-cells work
	Gamma (Brazil) variant	Vaccine works (NA only slightly reduced; T-cells working)	Vaccine works (NA only slightly reduced; T-cells working)	51% efficacy	Probably reflective of B.1.351 findings	Probably reflective of B.1.351 findings	<i>Non-hospitalized from original infection:</i> reduced-to-no antibody protection <i>Hospitalized:</i> protection similar to vaccine; T-cells work
	Delta & Kappa (India) variant	88% efficacy (UK) (4-fold decrease in NA)	Vaccine works (4-fold decrease in NA)	60% efficacy (UK)			
	Protection from severe disease	90% (clinical trial) 97-100% (real world)	100%	85% (100% after day 49)	100% (clinical trials)	100%	
Severe COVID19	Protection from hospitalization	100% clinical trial 94% real world; 80% after 1 dose (real world)	100% clinical trials 94% real world; 77% after 1 dose (US)	100% clinical trials	100% clinical trials 80% after 1 dose (real world)	100% clinical trials	
	Protection from death	100% (clinical trial) 99.99% (real world)	100% (clinical trial) 98.7% (real world)	100% clinical trials	100% clinical trials	100% clinical trials	
	Contingency plan for variants	Developing booster	Booster against B.1.351 works	Developing updated vaccine	Developing updated vaccine	Developing updated vaccine	Get a vaccine
	Asymptomatic (transmission) reduction**	72-95%	67-72%	74%	2% (SD/SD); 49% (among LD/SD)		
	Age	12+	18+	18+ (FDA warning for blood clots)	18+	18+	Not Applicable
	# doses	2 (3 weeks apart)	2 (4 weeks apart)	1	2 (4 weeks apart)	2 (3 weeks apart) 2 (4 weeks apart)	Not Applicable
Storage		-25 to -15 C	-25 to -15 C	2°C to 8°C	2°C to 8°C	2°C to 8°C	Not Applicable
Status of kid trials		Child ongoing (results expected Sept 2021)	Child ongoing	Enrollment for 6mo-11y start soon	Ongoing in UK	Enrollment open	Not Applicable

RCT= Randomized Control Trial; NA= neutralizing antibodies LD=low dose; SD=standard dose; J&J=Johnson and Johnson
 **== Be careful comparing these numbers across vaccines. These are VERY preliminary and studies greatly vary



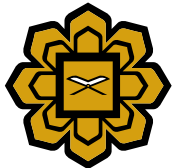
UK (AstraZeneca), 66 juta

	Jan 2021	Jun 2021*	Jul 2021*
Vaksin	3%	60%	69%
Kes(sehari)	881/juta	55/juta	702/juta
Kematian	13/juta	0.12/juta	0.65/juta

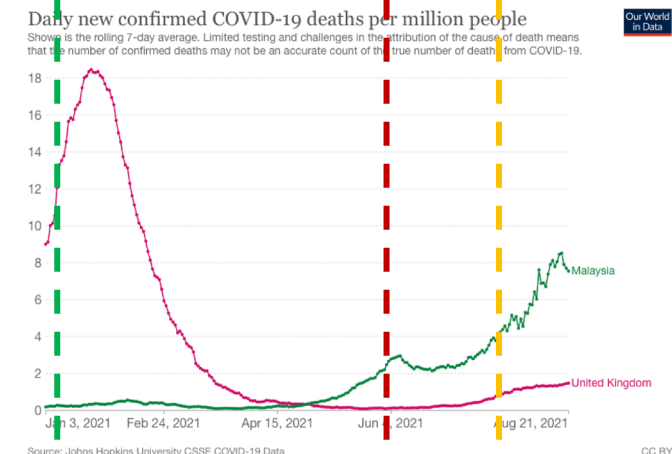
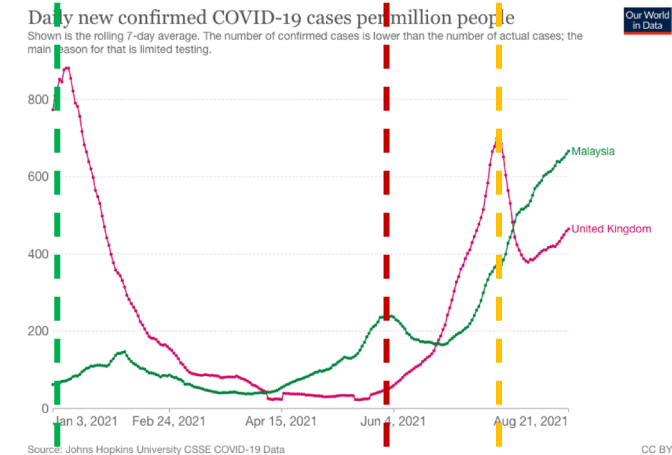
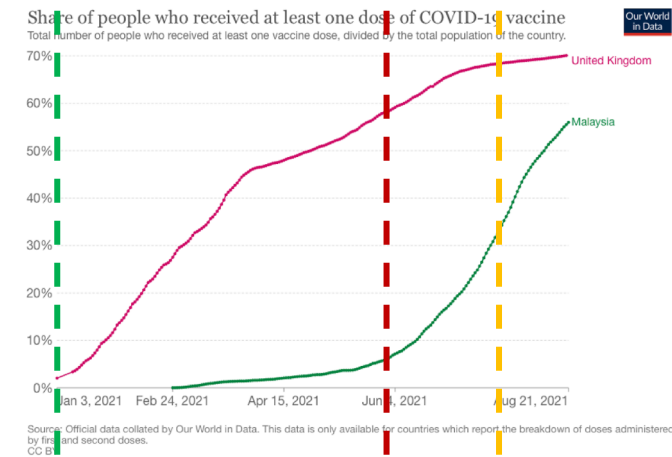
* Impak varian Delta



Max
65,000 case sehari
1800 kematian
sehari



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Peru (Sinovac)

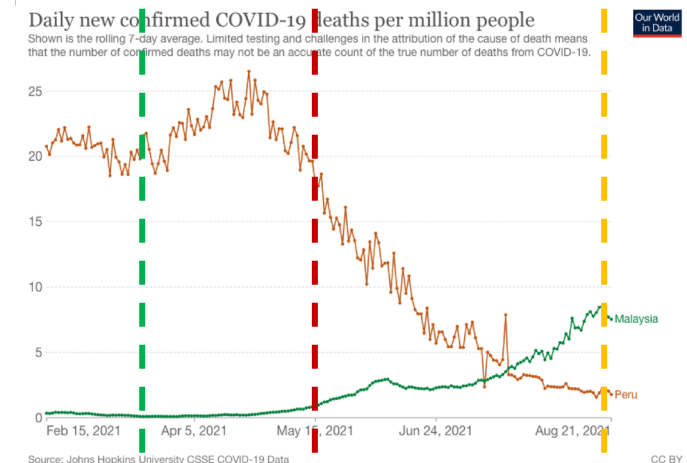
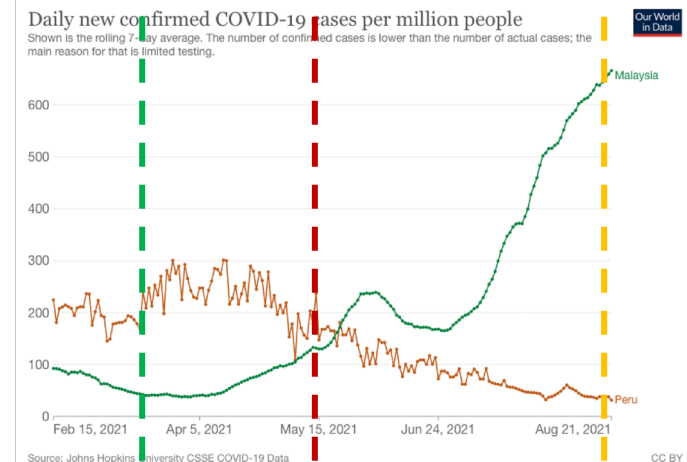
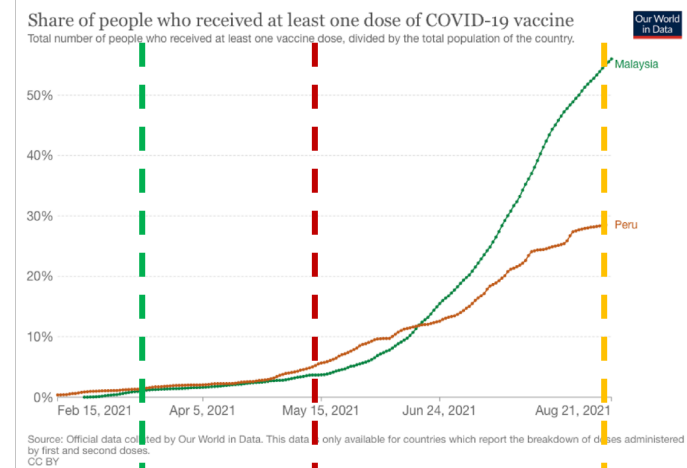
32 juta

	Mar 2021	Mei 2021	Aug 2021
Vaksin	1.5%	6%	28%
Kes	300/juta	150/juta	38/juta
Kematian	22/juta	18/juta	2/juta

- Tidak banyak kes varian Delta di Peru
- 80% kes sejak April dikaitkan dengan varian Lambda
- Di Peru, hampir 200,000 penduduk meninggal dunia disebabkan covid



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Adakah vaksin berkesan untuk delta variant?

Ya, vaksin masih berkesan($\pm 90\%$) mengurangkan kematian dan kemasukan di hospital dan ICU



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Israel says Pfizer Covid vaccine is just 39% effective as delta spreads, but still prevents severe illness

PUBLISHED FRI, JUL 23 2021 1:23 PM EDT | UPDATED FRI, JUL 23 2021 4:56 PM EDT



Berkeley Lovelace Jr.
@BERKELEYJR

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KEY POINTS

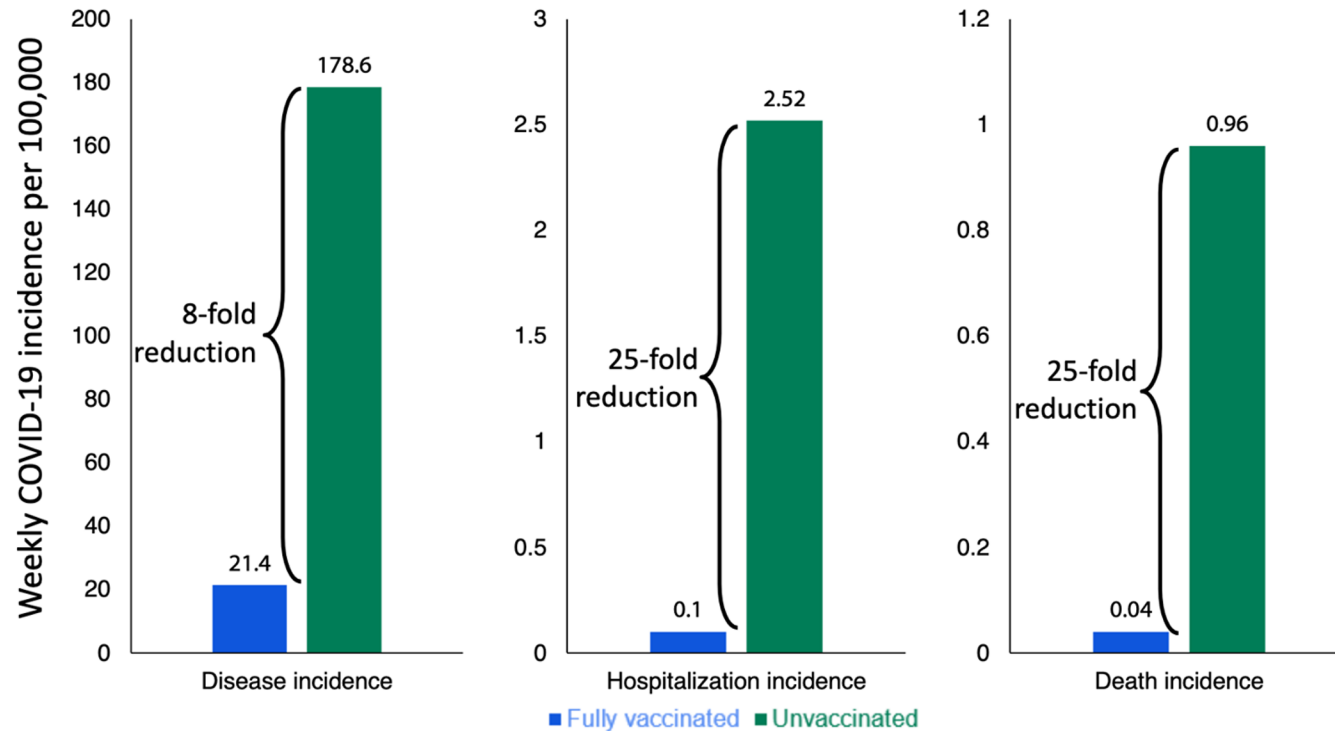
- Pfizer and BioNTech's Covid-19 vaccine is just 39% effective in Israel where the delta variant is the dominant strain, according to a new report from the country's Health Ministry.
- The two-dose vaccine still works very well in preventing people from getting seriously sick, demonstrating 88% effectiveness against hospitalization and 91% effectiveness against severe illness, according to the Israeli data.

Almost All U.S. COVID-19 Deaths Now in the Unvaccinated

By Damian McNamara

About 2,000 people a week in the U.S. are dying from COVID-19, mostly infected by the fast-spreading delta variant, according to a USA TODAY analysis of Johns Hopkins University data. About 99% of deaths today are people who did not get vaccinated. Patients dying in hospitals are telling loved ones they regret not getting the vaccine.

Greater risk of disease, hospitalization and death among unvaccinated vs. vaccinated people: National estimates

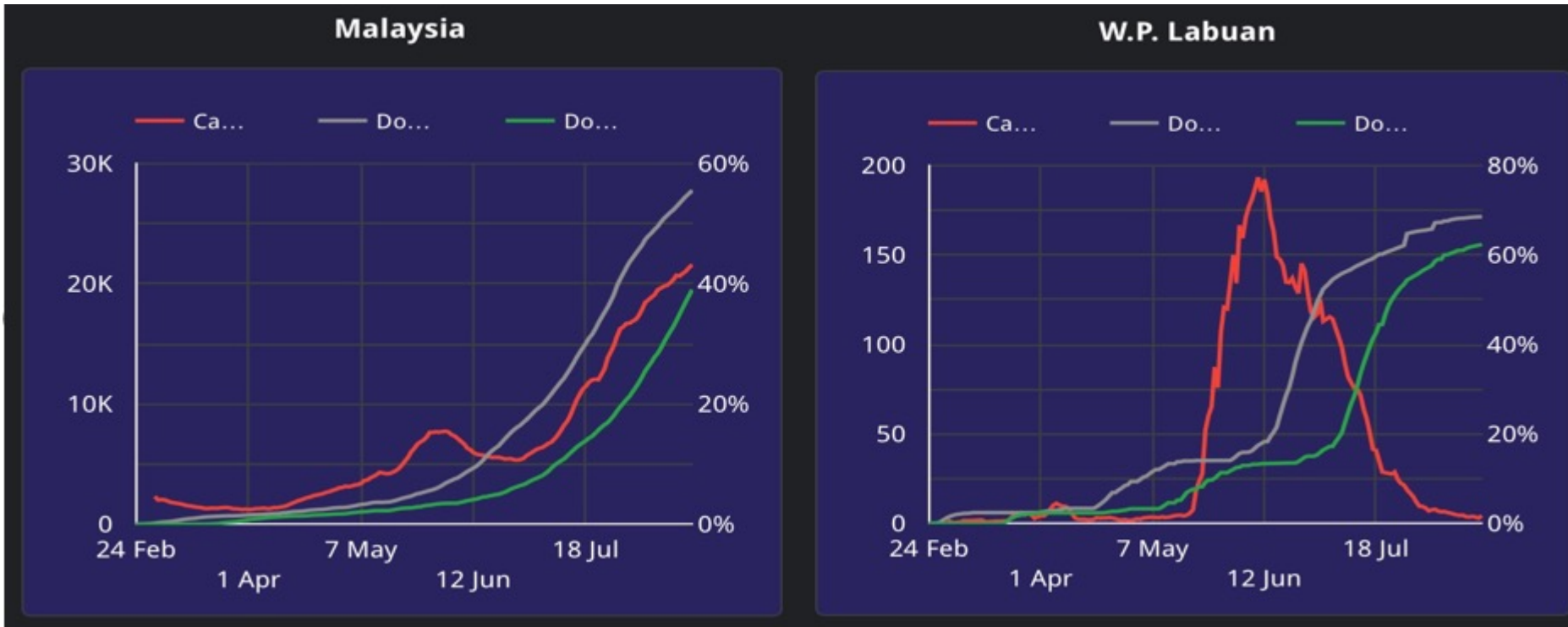


**At current incidence,
35,000 symptomatic
infections per week
among 162 million
vaccinated Americans**

Data from COVID Tracker as of July 24, 2021. Average incidence 100 cases per 100,000 persons per week. Vaccine effectiveness against symptomatic illness = 88% (Lopez Bernal et al. [NEJM 2021](#)), where risk is $[1 - VE]$ or 12%. Vaccine effectiveness hospitalization (or death) = 96% (Stowe et al. [PHE preprint](#)), where risk is $[1 - VE]$ or 4%. Rate in unvaccinated = Community rate/ $[(1 - \text{fully vaccinated coverage}) + (1 - VE) * \text{fully vaccinated coverage}]$. Rate in fully vaccinated = $(1 - VE) * \text{Rate in unvaccinated}$. Fully vaccinated coverage proportions were from COVID Data Tracker as of July 24, 2021 (50% for US).



Di Malaysia



Labuan ke Fasa 4 mulai Khamis

Oleh **Afiq Mohd. Shah** - August 24, 2021

👁 253

💬 0

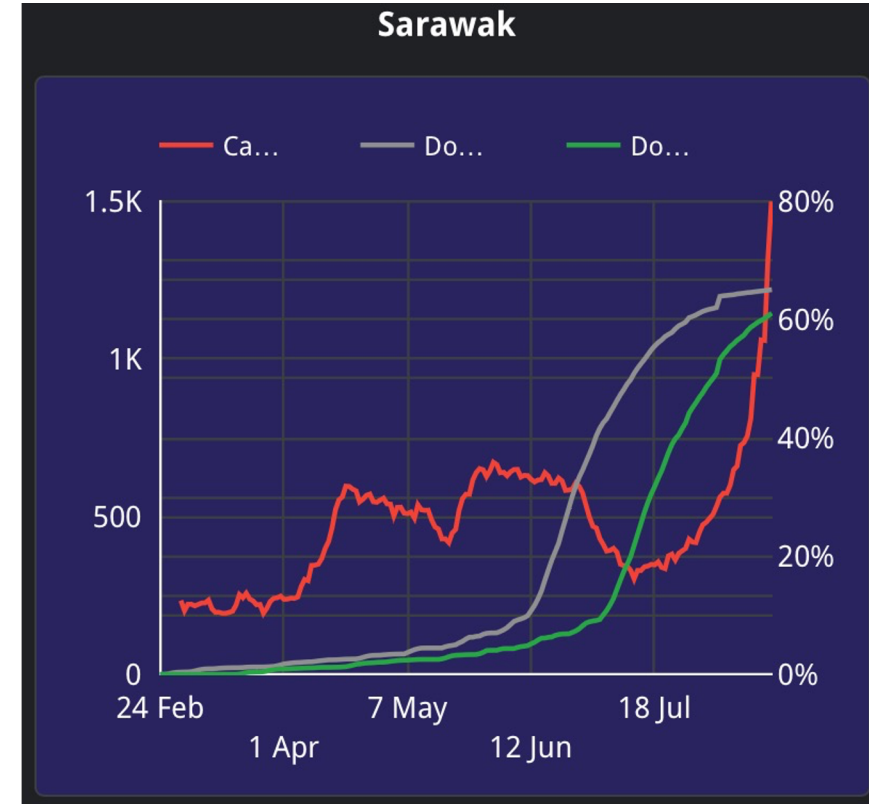


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Di Sarawak

- 🚢 90% penduduk dewasa sudah divaksinasi sekurang2 1 dose
- Kes bertambah



Di Sarawak

- Kebanyakan kes-gejala ringan
- Tiada kematian

Perbandingan Kategori Kes Positif Di Sabah & Sarawak 20/8/21

LAPORAN 20/8/21	SARAWAK	SABAH
JUMLAH KES POSITIF	2,548	2,738
Populasi Dewasa Lengkap 2 Dos Vaksin	83.6%	28.0%
Kategori 1	2,224	1,073
Kategori 2	323	1,601
Kategori 3	TIADA	10
Kategori 4	TIADA	4
Kategori 5	1	4
JUMLAH KATEGORI 3+4+5	1	18
Jumlah Kes Kematian	TIADA	17

Sarawak Covid19 Awareness Group

Perbezaan Kategori:

Kategori 1 - Tiada Gejala

Kategori 2 - Gejala Ringan

Kategori 3 - Jangkitan Paru-Paru

Kategori 4 - Kategori 3 + Memerlukan Oksigen

Kategori 5 - Ketegori 3 + Memerlukan Ventilator



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“Viral load” turun lebih cepat dengan vaksin (Delta)

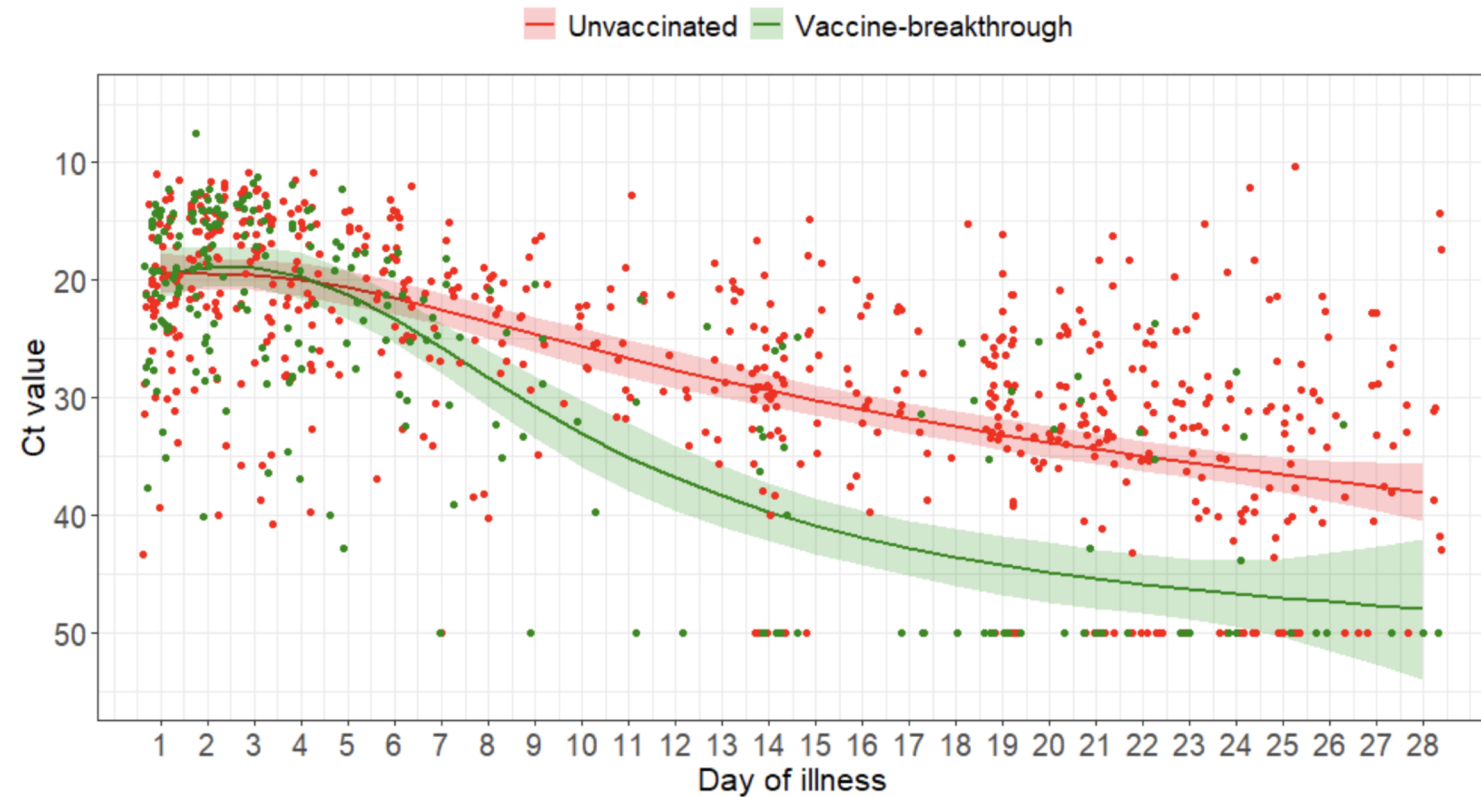


Figure 1: Scatterplot of Ct values and marginal effect of day of illness of COVID-19 B1.617.2 infected patients with 95% confidence intervals from generalized additive mixed model with interaction term between vaccination status and day of illness



Kesimpulan

- Vaksin sangat berkesan

1,517 Schoolchildren In Malaysia Have Lost Their Parents To COVID-19

According to the Ministry of Education, the numbers recorded are from March 2020 to August this year.



By Sadho Ram — 25 Aug 2021, 01:55 PM

Lapan beradik hilang ibu bapa akibat COVID-19 terima faedah bulanan PERKESO

Antivaksin akhirnya meninggal akibat Covid-19

FMT Reporters 26/7/2021

Like | 86



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INTERNATIONAL ISLAMIC UNIVERSITY MALAYSIA
يُونِيسَيْتِي إِسْلَامُ إِنْتَارَاغْشَا مَلِيسِيَا

Garden of Knowledge and Virtue

KULLIYAH OF MEDICINE

Keselamatan Vaksin

Assoc. Prof. Dato Dr. Ahmad Fadzil Abdullah

Pakar Pediatrik

Kulliyyah Perubatan, IIUM

Prof Dr How Soon Hin

Pakar Perubatan Respiratori

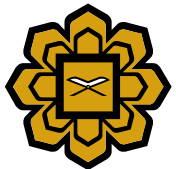
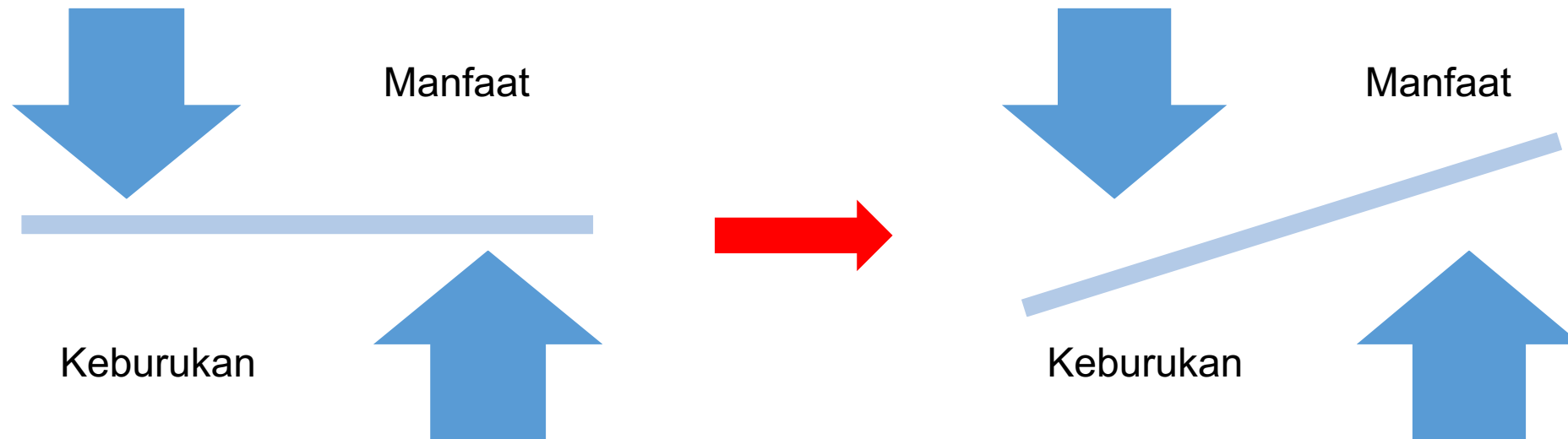
Kulliyyah Perubatan, IIUM

Asst. Prof. Dr. Norhidayah Kamarudin

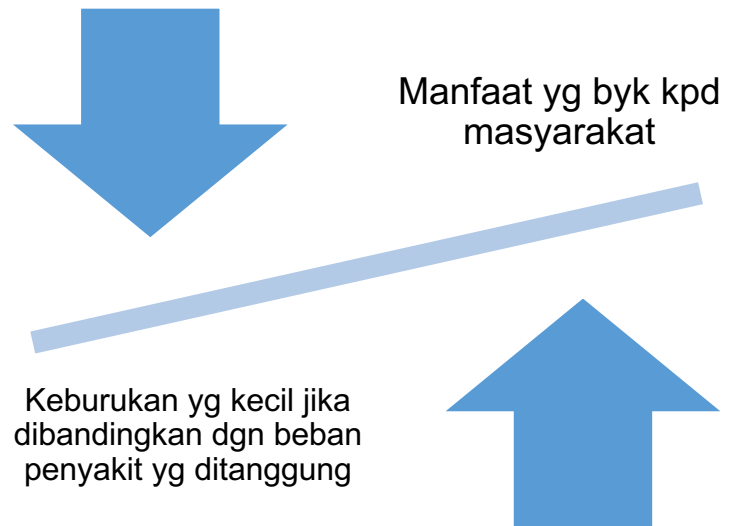
Pakar Patologi (Mikrobiologi Klinikal)

Kulliyyah Perubatan, IIUM

- Terlalu sedikit perbuatan dan tindakan manusia tiada kesan sampingan termasuk memakan ubat atau mengambil vaksin.



Apakah tanda-tanda vaksin tersebut di istilahkan selamat?



- Cth: Measles (Demam campak)

Risk of acquiring illnesses following infection versus risk following vaccination

	Measles infection ^a	Measles vaccine ^b
Otitis	7–9%	0
Pneumonia	1–6%	0
Diarrhoea	6%	0
Post-infectious encephalomyelitis	0.5/1,000	1/100,000 – million
SSPE	1/100,000	0
Anaphylaxis	0	1/100,000 – million
Thrombocytopenia	Not properly quantified ^c	1/30,000 ^d
Death	0.1–1/1,000 (up to 5–15%)	0



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Ujian Keselamatan Vaksin COVID-19

- Fasa 1 - pada haiwan yang hampir dengan manusia
 - Fasa 2 - pada sebahagian kecil manusia
 - Fasa 3 - pada sampel manusia dgn bilangan yg lebih besar
 - Fasa 4 - pemantauan berterusan selepas penggunaan vaksin
-
- Setiap vaksin akan melalui proses yg sama **TANPA pengecualian**.
 - Agensi regulatori vaksin yg memantau- **NPRA (Malaysia), FDA (US)**, FME (Eropah) dsbgainya di bawah pemantauan Pertubuhan Kesihatan Antarabangsa **(WHO)**.



Arab Saudi juga memerlukan semua Jemaah haji divaksinasi



Coronavirus

Saudi Arabia permits entry with Sinopharm, Sinovac vaccines after booster shots



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Kesan sampingan

Biasa seperti
mendapat 'flu'
sahaja

Pfizer-BioNTech COVID-19 Vaccine
VRBPAC Briefing Document

**Vaccine recipients had significantly
more side effects than placebo group.**

Table 19. Frequency of Unsolicited AEs with Occurrence in $\geq 1\%$ of Participants in any Treatment Group from Dose 1 to 1-month After Dose 2, Phase 2/3 Safety Population*, 16 Years of Age and Older

System Organ Class Preferred Term	BNT162b2 N=18801 n (%)	Placebo N=18785 n (%)	Total N=37586 n (%)
General disorders and administration site conditions	3521 (18.7)	737 (3.9)	4258 (11.3)
Injection site pain	2125 (11.3)	286 (1.5)	2411 (6.4)
Fatigue	1029 (5.5)	260 (1.4)	1289 (3.4)
Pyrexia (FEVER)	1146 (6.1)	61 (0.3)	1207 (3.2)
Chills	999 (5.3)	87 (0.5)	1086 (2.9)
Pain	455 (2.4)	36 (0.2)	491 (1.3)
Musculoskeletal and connective tissue disorders	1387 (7.4)	401 (2.1)	1788 (4.8)
Myalgia	909 (4.8)	126 (0.7)	1035 (2.8)
Arthralgia	212 (1.1)	82 (0.4)	294 (0.8)
Nervous system disorders	1158 (6.2)	460 (2.4)	1618 (4.3)
Headache	973 (5.2)	304 (1.6)	1277 (3.4)
Gastrointestinal disorders	565 (3.0)	368 (2.0)	933 (2.5)
Diarrhoea	194 (1.0)	149 (0.8)	343 (0.9)
Nausea	216 (1.1)	63 (0.3)	279 (0.7)



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Kesan sampingan vaksin COVID-19

- Pengalaman PPV SASMEC@IIUM Kuantan, sehingga 19 Ogos 2021:
 - 13,796 dos Pfizer, **83 (0.6%)** mengalami kesan sampingan. **Kesemua adalah ringan.**
 - 9836 dos Sinovac, **29 (0.3%)** mengalami kesan sampingan. **Kesemua adalah ringan kecuali 1 kes serius.** Hasil mesyuarat severe AEFI peringkat negeri mendapati ianya adalah **kejadian kebetulan yg tidak berkait secara langsung dgn vaksin.**
 - **Tiada kes kematian dilaporkan.**



Kesan sampingan teruk

- Terdapat beberapa kesan sampingan teruk yang dikenalpasti mempunyai kaitan langsung dengan vaksin COVID-19:
 - **Alahan yang teruk** (tidak spesifik & melibatkan semua jenis vaksin)
 - 2-5 kes setiap sejuta dos.
 - Semua kes dirawat dengan efektif dan tidak membawa kpd kematian.
 - **Masalah pembekuan darah- *thrombosis with thrombocytopenia syndrome*** (spesifik kepada Astra Zeneca)
 - 4 kes setiap sejuta dos
 - **Myokarditis**
- Amat jarang berlaku dan boleh dirawat.

There have been 157 reports here of suspected reactions to the Covid-19 vaccines severe enough to be life-threatening or result in hospitalisation, among other serious conditions.

However, no deaths have been linked to the jab, the Health Sciences Authority (HSA) said last Friday.

These "suspected serious adverse events" made up 0.004 per cent of the almost 3.7 million doses of Pfizer-BioNTech and Moderna jabs administered till May 23.



Research Paper

Thromboembolism risk of COVID-19 is high and associated with a higher risk of mortality: A systematic review and meta-analysis

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- Kajian kumulatif melibatkan 42 terbitan jurnal saintifik.
- Kejadian thromboembolism di kalangan pesakit COVID-19 yg dimasukkan ke ICU dan tidak masuk ICU.

COVID-19 Patient (non-ICU cases)	
Deep vein thrombosis	20%
Venous thromboembolism	21%
Pulmonary embolism	12%
Arterial thromboembolism	2%



Does the vaccine cause thrombosis (blood clots)?

An extremely rare specific form of blood clot in the cerebral veins (cerebral venous sinus thrombosis) and thrombocytopenia (low platelets) has been noted following coronavirus vaccination with the Astra Zeneca vaccine. The Medicines Healthcare Regulatory Agency ([MHRA](#)) has concluded that the evidence of a link with the Astra Zeneca vaccine is stronger, but further work is needed. Based on figures from 31st March 2021 around 4 people develop this condition for every million doses of the Astra Zeneca vaccine given. It tends to occur between 4 days and 2 weeks following vaccination. Data suggest there may be a slightly higher incidence reported in the younger adult age groups. There are currently no known risk factors for this extremely rare condition. The Joint Committee for vaccination and immunisation ([JCVI](#)) on the 7 May 2021 advised that it is preferable for adults <40 years of age without an underlying health condition that puts them at higher risk of severe COVID-19 disease to be offered an alternative COVID-19 vaccine (Pfizer or Moderna). MHRA advice states that the benefits of vaccination continue to outweigh any risks but advises careful consideration to be given to those who are at higher risk of specific type of blood clots because of their medical condition.

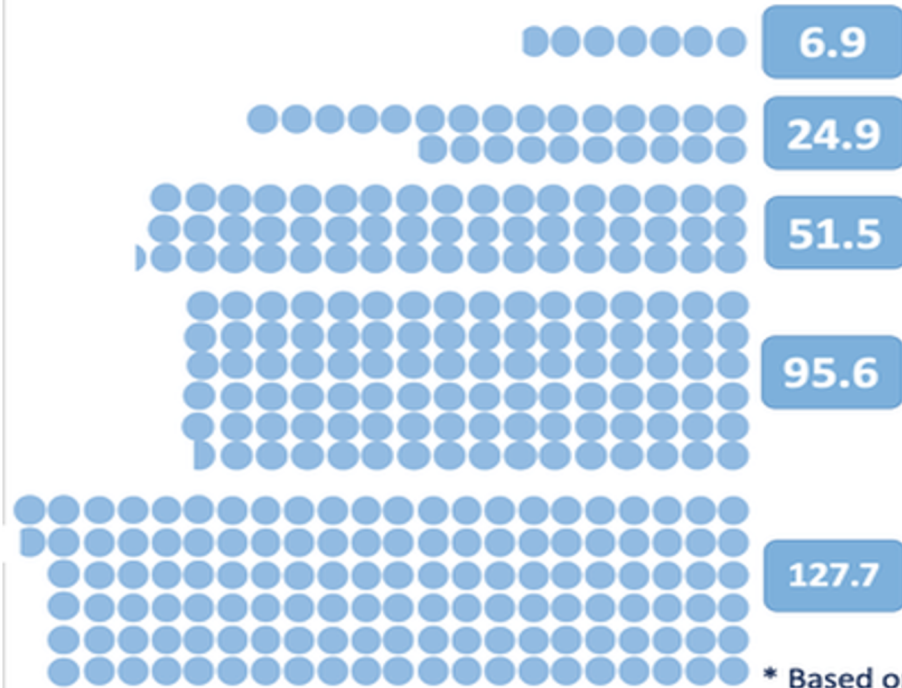


Weighing up the potential benefits and harms of the Astra-Zeneca COVID-19 vaccine

**For 100,000 people
with high exposure risk***

Potential benefits

ICU admissions due to COVID-19 prevented
every 16 weeks:



Age group

20-29yr

30-39yr

40-49yr

50-59yr

60-69yr

Potential harms

Specific blood clots due to the vaccine:

1.1

0.8

0.5

0.4

0.2

* Based on coronavirus incidence of 20 per 10,000 per day: roughly UK at peak of second wave




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Keradangan jantung (Myocarditis)

- Dilaporkan dikalangan remaja yg menerima Pfizer (450 kes/sejuta dos).

Age groups	Overall reporting rate per million doses			Reporting rate in females per million doses			Reporting rate in males per million doses		
	All doses	Dose 1	Dose 2	All doses	Dose 1	Dose 2	All doses	Dose 1	Dose 2
12-17 yrs	18.1	5.3	37.0	4.2	1.1	9.1	32.4	9.8	66.7
18-24 yrs	15.9	4.8	28.4	3.6	1.5	5.5	30.7	8.7	56.3
25-29 yrs	6.7	2.5	10.8	2.0	0.8	2.6	12.2	4.5	20.4
30-39 yrs	4.2	1.7	5.6	1.8	1.4	1.8	6.9	2.0	10.0
40-49 yrs	2.7	0.9	3.8	2.0	0.9	2.8	3.5	1.0	5.1
50-64 yrs	1.7	1.0	2.0	1.6	1.0	1.8	1.9	1.0	2.3
65+ yrs	1.1	0.7	1.3	1.1	0.6	1.2	1.2	0.7	1.4

 Myocarditis/pericarditis reports per million mRNA vaccine doses administered by sex and dose number with no restrictions on post-vaccination observation time



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Boleh pulih sendiri

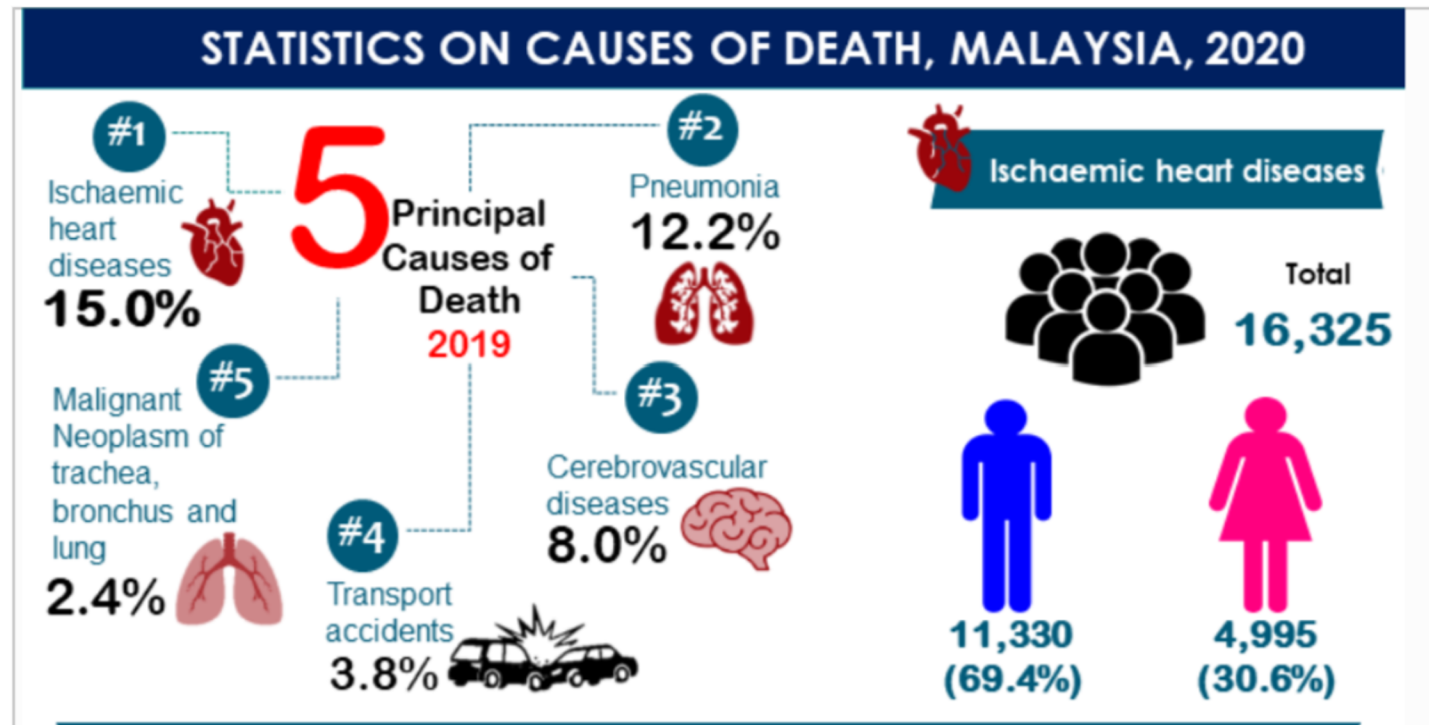
- Rare cases of **myocarditis**, a heart muscle inflammation, have been seen in men under 25 after receiving the second dose of the Pfizer-BioNTech Covid-19 vaccine, a panel of Israeli researchers reported to the Ministry of Health. Most cases were mild and resolved within a few weeks.

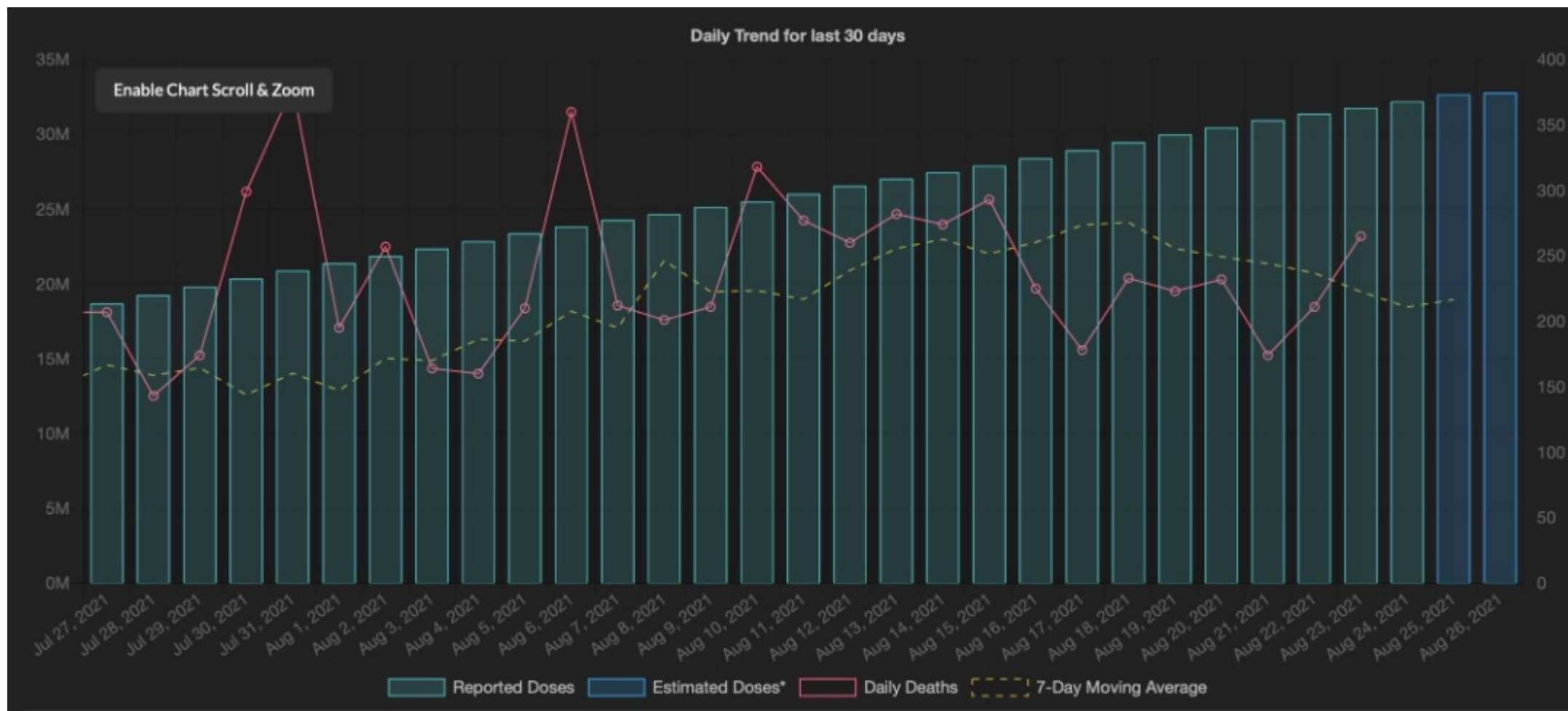


Kematian selepas vaksin

- 2019 (sbm COVID-19 vaksin):
 - 173,000 kes kematian
 - Purata 474 kematian sehari:
 - 45 serangan jantung
 - 24 stroke
 - 12 kemalangan

- Adakan selepas disuntik vaksin, seseorang itu mati akibat kemalangan, adakah kemalangan ini disebabkan oleh vaksin?
- Ini ialah **kebetulan (co-incidental)**





The source: <https://covidvax.live/location/mys>



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Di US, drpd 189 juta dos vaksin, 3486 (0.0016%) kes kematian dilaporkan selepas vaksin. Kesemua siasatan mendapati tiada kes kematian dikenalpasti terjadi disebabkan oleh vaksin.

COVID-19 Situation Report, n.49 (26 April 2021), Pan American Health Organization, WHO

"The CDC recommends people age 12 and older get the COVID-19 vaccine. The data **from almost 75,000 clinical trial volunteers and over 415 million doses administered** have shown that the vaccine is overwhelmingly safe."



Kesimpulan

- Penggunaan vaksin adalah di bawah **pemantauan yg berterusan**.
- Hanya **vaksin yg selamat** shj yg dilesenkan utk penggunaan.
- **Tidak wujud konspirasi** dan tiada badan-badan nasional/ antarabangsa yg sengaja membenarkan penggunaan vaksin yang tak selamat dikalangan rakyat mereka.

